

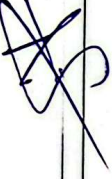
MEETING OF GRIEVANCE COMMITTEE TO ADDRESS THE GRIEVANCES RECEIVED IN BULK PURCHASE OF MEDICINES ITEMS FOR THE YEAR 2025-26.

Dated: 22.1.26

Grievance Committee meeting to address the Grievances received in Bulk Purchase of Medicines for the year 2025-26 was held on 22.1.26 in the office of the Chairman Grievance Committee Prof. Dr. Muhammad Hanif Mian Professor of Orthopedics, Lahore General Hospital Lahore.

2. The Following members attended the meeting:
 1. Dr. Muhammad Hanif Mian, Prof. of Orthopedics **Chairman**
 2. Dr. Atif Shehzad, Prof. of Dermatology **Member**
 3. Prof. Khurram Saleem, Prof. of Medicine **Member**
 4. Dr. Muhammad Kareem Ullah , Associate Prof. of Surgery **Member**
 5. Mst. Mahpara Uzair, Chief pharmacist **Member**
 6. Mr. Muhammad Ali Biomedical Engineer **Member**
3. The proceeding of the meeting was commenced with the recitation from the Holy Quran.
4. The committee after briefed discussion and hearing the firm's representatives unanimously decided the grievances as under;

Sr. No	Grievance presented by firm in PPRA	PPRA Decision	GRC Decision
1	<p>The firm M/s Pharmawise Labs challenged the decision of LGH GRC before PPRA, contending that items at T.E 396 and 398 in the LGH Bulk Tender 2025-26 were declared responsive by the TEC and hold valid DRAP approvals. The firm objected to GRC's declaration of the items as non-responsive on the grounds of "poor quality," arguing that quality assessment lies with DTL and note their products are widely approved in major Punjab hospitals. The firm requests reconsideration of matter.</p>	<p>As per Order No. L&M(PPRA)290/2025/Com dated 18.11.25, PPRA observed that LGH GRC decision was not based on scientifically validated evidence, as the procuring agency lacks the mandate to conduct clinical trials. Accordingly, PPRA set aside the decisions of the TEC & GRC and directed LGH to reconstitute the GRC with two independent members, one external technical expert and one administrative representative, to re-examine the case in accordance with technical specifications, bidding documents and applicable procurement rules, after providing the firm an opportunity of hearing.</p>	<p>In pursuance of PPRA Order No. L&M(PPRA)290/2025/Com dated 18.11.2025, the firm's representative attended the meeting and presented their stance, which was duly heard by the newly constituted GRC, including independent and external experts. GRC observed that, as per PPRA's decision, the procuring agency (LGH) lacks the mandate to conduct independent clinical trials and that rejection based on subjective "clinical experience" stands superseded by regulatory compliance. The GRC further held that under the Drugs Act, 1976 and the Punjab Procurement Rules, 2014, the quality of medicines is legally established through DRAP registration and verified post-procurement on a batch-wise basis by the Punjab Drug Testing Laboratories (DTL). The firm provided purchase orders from other Punjab teaching hospitals for FY 2025-26 to confirm market standing and clinical acceptance, and submitted "Standard Quality" DTL reports of supplied batches. Accordingly, the Committee, in line with the GRC's decision and after noting that the items are DRAP-registered and compliant with regulatory requirements, unanimously declared M/s Pharmawise Labs RESPONSIVE for T.E. Nos. 396 and 398, with each batch supplied to LGH to be tested by the Punjab Drug Testing Laboratories (DTL) prior to use as already stipulated in the bidding documents.</p>

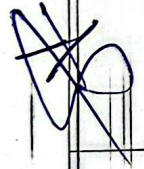
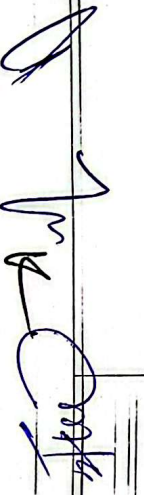




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Sr. No	Grievance presented by firm in PPRA	PPRA Decision	GRC Decision
2	<p>M/s 3N Lifemed Pharmaceuticals filed an appeal before PPRA against its non-responsive declaration of hemodialysis concentrates at TE 401 by LGH GRC, contending that the decision wrongly treated international certifications as mandatory, ignored its valid DRAP license, ISO compliance, and past satisfactory supply to LGH, and infringed constitutional rights. The firm requested that the GRC decision be set aside and that it be declared responsive.</p>	<p>As per PPRA Order No. L&M(PPRA)288-A/2025/com dated 28.10.25, PPRA decided to set aside the decision of GRC and directed the procuring agency to re-evaluate the complainant's bid strictly in accordance with the evaluation criteria after seeking clarification from DRAP.</p>	<p>In compliance with PPRA Order No. L&M(PPRA)288-A/2025/Com dated 28.10.2025, the firm's representative attended the meeting and presented submissions, which were duly heard by the Committee. The firm was granted three (03) days to submit relevant raw-material import documents along with valid DRAP clearance certificates. Upon submission of the import documents and clearance certificates issued by the Drug Regulatory Authority of Pakistan (DRAP), M/s 3N Lifemed Pharmaceuticals demonstrated that its products comply with the prescribed regulatory requirements. The DRAP clearance certificates substantiate that the raw material has been approved by the competent regulatory authority with respect to safety, quality, and applicable technical standards.</p> <p>The firm also placed reliance on the previous decision pertaining to Gujranwala Medical College Teaching Hospital, Gujranwala, vide PPRA Order No. L&M(PPRA)226/2025/Com dated 26.09.2025.</p> <p>Further, in light of the PPRA Order relating to Pakistan Kidney and Liver Institute and Research Center (vide No. L&M(PPRA)275/2025/Com dated 13.01.2026), the GRC observed that professional misconduct was not stipulated as a knock-down criterion in the bidding documents, and since the matter before CCP remains sub judice, the same cannot form valid grounds for disqualification of the firm.</p> <p>The Committee also considered the PPRA recommendation holding that the clause mandating international quality certification for local manufacturers is discriminatory, particularly in view of DRAP's clarification letter dated 02.04.2024, which states that such certification is not mandatory for the manufacture and marketing of medical devices in Pakistan. After due deliberation, the Committee unanimously resolved that the impugned clause shall not be applied to local manufacturers and that the tender shall be adjudicated on non-discriminatory criteria in accordance with PPRA Rules and DRAP regulations. Pursuant to PPRA directions, letters were issued to DRAP seeking clarification on the above-mentioned matters; however, despite the lapse of more than one month, no response has been received to date.</p> <p>The Committee further observed that any additional delay in the procurement of these life-saving items would be against the public interest. Accordingly, in view of aforesaid clarifications, the GRC hereby declares M/s 3N Lifemed Pharmaceuticals as RESPONSIVE.</p>

Sr. No	Grievance presented by firm in PPRA	PPRA Decision	GRC Decision
3	<p>M/s Sehat Medical Devices Pvt. Ltd. challenged the LGH GRC decision before PPRA, citing disqualification based on "long length tubing"</p> <ol style="list-style-type: none"> 1. An un-defined specification 2. Validity of its cGMP certification 3. Non-mandatory CE requirements for local manufacturers, <p>The firm has requested for restoration of technical responsiveness.</p>	<p>As per PPRA Order No. L&M(PPRA)283/2025/com dated 17.11.25, PPRA has set aside the decisions of TEC & GRC and remanded the representation filed by the firm back to the GRC. The matter is now pending before the GRC, which will re-examine all contentions raised by the complainant, strictly in accordance with the law, after providing the firm an opportunity of hearing.</p>	<p>In pursuance of PPRA Order No. L&M(PPRA)283/2025/com dated 17.11.2025, the firm's representative attended the meeting and presented their stance, which was duly heard. The samples of IV set submitted by the firm were found to be in conformity with the advertised specifications of LGH and were accordingly approved.</p> <p>The Committee further observed that the bidder's cGMP certificate, valid up to 08 May 2025, remained legally in force on the tender submission deadline date, and that its renewal was under process with DRAP at that time and has now been renewed.</p> <p>Regarding the CE requirements for local manufacturers, the Committee considered the matter in light of the PPRA decision clearly declaring the clause, requiring international quality certification for local manufacturers, as discriminatory, supported by DRAP's clarification that such certification is not mandatory. Accordingly, the Committee unanimously decided that the impugned clause shall not be applied to local manufacturers, and the tender shall proceed on non-discriminatory criteria in line with DRAP regulations and PPRA Rules, which shall serve as the <i>modus operandi</i> for re-evaluation. Accordingly the GRC, in pursuance of the PPRA decision and the <i>modus operandi</i> adopted by the Committee, re-evaluated the matter and declared the firm M/s Sehat Medical Devices Pvt. Ltd, RESPONSIVE.</p>

Sr. No	Grievance presented by firm in PPRA	PPRA Decision	GRC Decision
4	<p>The firm M/s Lablink Enterprises challenged the LGH GRC decision before PPRA, stating that TEC had initially declared it responsive for Items at T.E 403 and 404, but the GRC Chairman declared it non-responsive citing patient safety concerns, including reliance on ICU/end-user feedback, which was not part of the tender criteria.</p> <p>The complainant also raised a grievance against the responsiveness of M/s IBL Health Care, citing technical non-compliances including an expired distribution agreement, incorrect manufacturer details in the MDR Extension/CE certificate, and FSC not issued by a competent authority.</p>	<p>As per Order No.L&M(PPRA)293/2025/Com dated 17.11.25, PPRA is of the view that the GRC decision was not based on scientific evidence (clinical trial based), as the procuring agency is not authorized to conduct such scientific trials, which require controlled, regulated and ethical environments beyond its mandate. Accordingly, PPRA decided to set aside the decisions of the TEC and GRC. LGH has been directed to re-constitute the GRC by including two independent members—one technical expert from outside the organization and one representative from the administrative department—to re-examine the case in accordance with the technical specifications and tender rules, after providing the firm an opportunity of hearing.</p> <p>Firm's complaint against M/s IBL Health Care: PPRA advised that verification of the FSC issued by the China Chamber of Commerce falls within DRAP's mandate, and clarification may be sought from DRAP.</p>	<p>In compliance with PPRA Order No. L&M(PPRA)293/2025/Com dated 17.11.2025, the re-constituted Grievance Redressal Committee re-examined the matter with participation of all firms. All firms' representatives attended the meeting and presented their respective stances, which were duly heard by the Committee. The Committee observed that reliance on subjective ICU/end-user feedback or independent clinical trials is not permissible; hence, the earlier rejection of M/s Lablink Enterprises on such grounds stands superseded. It was noted that M/s Lablink Enterprises' IV sets are duly registered with DRAP under the Drugs Act, 1976, and that product quality is to be verified post-procurement through batch-wise testing by Punjab Drug Testing Laboratories (DTL) in accordance with Punjab Procurement Rules, 2014. Moreover, M/s Lablink Enterprises submitted purchase orders of FY 2024-25 issued by LGH itself, along with satisfactory DTL reports declaring the supplied batches as "Standard Quality," thereby confirming regulatory compliance. In the absence of any adverse DTL report or regulatory non-compliance, the Committee found no lawful basis to declare Lablink non-responsive and recommended that the bid be treated as technically responsive and processed further as per rules, with each batch supplied to LGH to be tested by the Punjab Drug Testing Laboratories (DTL) prior to use, as already stipulated in the bidding documents.</p> <p>Regarding to M/s IBL Health Care case the firm was granted a period of three (03) days to submit the Free Sale Certificate (FSC) issued by the competent regulatory authority of the country of origin. In parallel, pursuant to PPRA directions, letters and reminders were issued to DRAP seeking clarification on the matter; however, despite the lapse of more than one month, no response has been received from DRAP to date.</p> <p>Although the FSC submitted by M/s IBL Health Care, issued by the relevant competent authority, was accepted by the GRC, but the Committee did not accept the subsequently submitted renewed distribution agreement and the proof of request made to DRAP for change of manufacturer details in the MDR/CE certificate. Accordingly, M/s IBL Health Care was declared non-responsive.</p> <p>Consequently, to ensure uninterrupted availability of this essential medical device, the Committee unanimously declared M/s Lablink Enterprises responsive and M/s IBL Health Care non-responsive for T.E. Nos. 403 and 404</p>

Eng. Muhammad Ali
Biomedical Engineer
Member

Mst. Mahpara Uzair
Chief Pharmacist
Member

Dr. Khurram Saleem
Prof. of medicine
Member

Dr. Muhammad Hanif Mian,
Prof. of Orthopedics
Chairman

Mr. Usayb Sardar Ghori
CH & UCHS, Lahore
Member

Mr. Muhammad Kareem ullah
Associate Prof. of Surgery
Member

Dr. Atif Shehzad
Prof. of Dermatology