Participants:

1. Prof. Dr. Nasir Chaudhary

Head of Ophthalmology Department Unit-H Mayo Hospital Lahore

2. Dr. Rabia Rathore
Associate Professor of Medicine/Head of WMW Mayo Hospital Lahore

3. Dr. Umer Nazir Member

Assistant Professor of Plastic Surgery Mayo Ilospital Lahore

Deputy Drugs Controller Mayo Hospital Lahore

4. Ms. Kanwal Javed Secretary

Deputy Drugs Controller Mayo Hospital Lahore

5. Mr. Muhammad Jawad Bhatti Member

Proceedings:

Meeting started with the recitation from the Holy Quran. The Chairman, Grievances Committee Mayo Hospital Lahore welcomed all the participants.

ITEM NO. 01:

GRIEVANCE SUBMITTED BY M/S ALLIED DISTRIBUTORS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

With reference to the subject matter and your TEC report T.E. # 69 & 114 for the fiscal year 2025-26, we would like to highlight the following points for your kind consideration:

- The products in question are of a highly sensitive nature, as are used for general anesthesia-an area directly impacting patient life and safety.
 Therefore, it is difficult to believe that locally manufactured products can match the quality of products imported & USFDA approved.
- 2. Even the USFDA mandates the use of specific USP-compliant glass bottles for this product due to their beneficial properties, such as stability, transparency, and recyclability. The resillence of Piramal's USP glass bottles has been demonstrated through drop tests conducted by independent laboratories in both India and the USA, using Piramal's Isoflurane and Sevoflurane bottles.
- 3. Given the product's critical nature, it is essential to use virgin glass bottles. However, In Pakistan, there is no guarantee that the other firm

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is using virgin glass for packaging. Piramal in contrast, exclusively uses virgin USP glass bottles to ensure product integrity and safety.

- 4. The use of recycled glass bottles can lead to the formation of Lewis acid, which is associated with serious health risks including respiratory, metabolic, and blood acidosis. Additionally, Lewis acid formation can lead to vaporizer malfunction, posing further risk due to incorrect drug administration.
- Our firm ensures the highest safety standards by using only virgin USP glass bottles, thereby mitigating these life-threatening risks.
- 6. In addition to ensuring safety, we are willing to provide your esteemed institution with at least 10 vaporizers for Sevoflurane & 10 for Isoflurane, each costing approximately one million rupees, on a loan basis. This includes complete servicing, such as calibration, for the provided equipment.
- Our products offer a shelf life of five years, which is a testament to the stability and quality of our manufacturing process.
- 8. The extended shelf life also provides a significant logistical advantage by reducing the risk of product expiry before consumption when ordering in bulk.
- 9. In comparison, the competing firm offers only a two-year shelf life.
- Piramal's Isoflurane & Sevoflurane are manufactured and bottled in a single state-of-the-art facility in the USA.
- 11. Conversely, our competitor produces the bulk material in one country and ships it in large drums to be bottled in another, which may compromise product integrity.
- 12. Piramal's Isoflurane and Sevoflurane meet all USP impurity specifications. Supporting documentation can be provided upon request.

13. Every time we receive a batch in Pakistan, random samples are sent to the Central Drug Laboratory (CDL) for analysis. Only after receiving a

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satisfactory report from CDL do we release the batch for sale. CDL reports attached.

- 14. No other firm in the market follows such rigorous self-imposed quality checks, underscoring our commitment to safety in this life-critical domain.
- 15. Last year, the competing firm was awarded the SIMS tender but failed to supply the medication and did not submit the required performance guarantee.
- 16. It has been observed that the same firm quoted a price above the MRP in PINS, which was subsequently rejected. Incorrect pricing was also reported at Shaukat Khanum Hospital and was later corrected.
- 17. The competing firm does not hold any international certifications.
- 18. They import bulk product in drums and refill it into bottles, while misrepresenting this process as manufacturing.
- 19. Reports have indicated that the anesthesia depth achieved with their products is suboptimal.
- 20. The current tender qualification criteria for this firm appear relatively lenient. For sensitive products like Isoflurane & Sevoflurane, international certifications such as USFDA and MHRA should be mandatory.
- 21. Qualification criteria for sensitive drugs should be product-specific, focusing on quality, safety, and regulatory compliance, rather than being based merely on the identity of the importer or manufacturer.
- 22. The Criteria of the Evaluation of Isoflurane & Sevoflurane should be same for Importer & Manufacturer.

In light of the above, we are confident that your esteemed office will give due consideration to our USFDA-approved Restane (Isoflurane) & Sojourn (Sevoflurane) for inclusion in the current year's tender.

Decision:

Mr. Mr. Abdul Aziz, Senior Territory Manager & Mr. Mirza Javaid Baig, Sales

Manager of firm presented the above-mentioned grievance before the

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Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has qualified M/S Allmed in these items. The committee also observed that Drug Regulatory Authority Islamabad registers the drug after confirming all necessary quality pre-requisites and the supply of firm also has to pass through testing at Drug Testting Laboratory Lahore. The committee regretted the grievance.

ITEM NO. 02:

GRIEVANCE SUBMITTED BY M/S STALLION PHARMACEUTICALS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO **HOSPITAL, LAHORE)**

GRIEVANCE DETAIL:

With reference to your Technical Evaluation of Tender Medicines, we would like to take your attention towards our product: Tender Item# 09, 63,122: This is very surprising for all of us that the above-mentioned product is declared non-responsive while we have been provided all the required documents in your tender bidding documents. According to your technical evaluation report here are some points we want to share with that we did not get marks,

- 1. We awarded 0 Mark in Experience of Public Sector column, on Page#167-170 in our bidding documents that we submitted, Details of Sales of this product mentioned on Stamp paper, while on Page# 171-241 purchase orders and Delivery Challans attached for your reference. Kindly award full marks in this column.
- 2. For Item# 122 we get 0 mark awarded in Availability of Product at Major Chain Pharmacies. We request you to please review this part again and give us marks accordingly. On Page#353-373 in our bidding documents Details of Availability of Product at Major Chain Pharmacies is attached.
- 3. And we submitted our medicine samples for the tender, but they have been rejected. We kindly request you to please reconsider our samples for Item #09 And 63. And we confirm that we will provide water for injection with these items. And we also submitted undertaking in this

regard.

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In the light of the above facts we are confident that status of our above mentioned will be Declare as responsive..

Decision:

Mr. Muhammad Saeed, Institutional Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified bid for T.E. 9, 63 due to failure in clause (vi) of compulsory parameters and T.E. 122 due to less marks in marking criteria.

Compulsory parameters:

The committee observed that the institution has advertised T.E. 9 & 63 with WFI in individual pack. While the firm did not submit samples with WFI for T.E. 84 & 122. However, the firm provided WFI along with samples of T.E. 84 & 122. The committee observed that the firm has not quoted WFI for T.E. 9 while the firm has quoted solvent with T.E. 63 in its technical bid. The firm also gave an undertaking on its letterhead that it will supply the injections with WFI. The committee decided to declare T.E. 63 responsive in clause (vi) of compulsory parameters.

Ordinary parameters:

The firm claimed that T.E. 122 qualifies the marking requirements of Ordinary Parameters. The firm claimed that its API source is UFDA approved and TEC has marked zero marks in clause (1) of ordinary parameters. The committee observed that the API source: Shandong Anxin Pharmaceutical Co., Ltd. is listed on FDA website and decided to award 10 marks in clause (1) of ordinary parameters.

The firm stated that it has the sufficient public experience for T.E. 122 to secure marks in clause (3) of ordinary parameters. The committee observed that the firm has attached some documents to demonstrate experience in public sector. The firm stated that the figures in undertaking had become faded inadvertently, but the Purchase orders and Delivery challans have been attached in the bid. The firm also provided some documents in the

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grievance that were established after date of tender opening and were rejected. The firm attached PO No. 2175 dated 29.10.2024 to supply 2410 injections to Chief Executive Officer (CEO) District Health Authority (DHA) Faisalabad but the delivery challan did not contain the claimed product. PO No. 11030 dated 23.09.2023 for supply of 12000 injections to M/S Aziz Bhatti Shaheed teaching Hospital Gujrat but the DC No. 12758 was undated and was not aligned with the requirements of the Purchase order - hence regretted; PO No. k04220000970 dated 14.06.2024 and DC No. 13236 dated 25.08.2024 for supply of 11000 injections at Lady Reading Hospital MTI Peshawar that was accepted; PO No. K04230002361 dated 18.12.2023 & DC NO. 12743 dated 14.03.2024 for supply of 14000 injections at Medical Teaching Institution Abbottabad that was accepted. The committee observed that the firm has supplied more than 30 % of quoted product at public institutions and awarded 3 marks in section (3) of ordinary parameters.

The firm claimed that it has attached the invoices of their distributor i.e. Punjab Traders to different chain pharmacies i.e. Invoice No. 50145 dated 23.01.2023, Inv No. 54255 dated 10.06.2023, Inv No. 59636 dated 10.12.2023 to Clinix Central Warehouse Lahore; Invoice No. 51348 dated 23.01.2023, Inv No. 55389 dated 28.05.2023, Inv No. 60136 dated 30.12.2023 for supply at Fazal Din Pharma Plus Lahore; Invoice No. 53615 dated 02.02.2023, Inv No. 56236 dated 03.07.2023, Inv No. 61316 dated 11.12.2023 for supply at Green Plus Pharmacie Lahore; Invoice No. 52645 dated 19.02.2023, Inv No. 55236 dated 27.08.2023, Inv No. 60616 dated 21.12.2023 for supply at New Mehmood Pharmacy Lahore; and Invoice No. 53119 dated 27.01.2023, Inv No. 57236 dated 11.08.2023 for supply at Servaid Pharmacy Lahore. The committee awarded 5 marks for T.E. 122 in clause 11 of ordinary parameters. T.E. 122 stands responsive in Ordinary parameters.

In conclusion T.E. 63 & 122 quoted by the firm stands responsive.

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ITEM NO. 03:

GRIEVANCE SUBMITTED BY M/S HIMMEL PHARMACEUTICALS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We would like to respectfully submit our grievance regarding the technical evaluation report of Mayo Hospital Lahore in which our products have been declared non- responsive in Compulsory Parameters, clause No. viii for T.E. 48 & 49 (Inj. Enoxaprin 40mg & 60mg). It is submitted that the biosimilar studies is hereby attached which was not uploaded indue to a huge number of pages of biosimilar study and the EPADS does not allow file size exceeding 200MB size. It is humbly requested that for healthy competition and of provision of quality medicines to the patients the request of biosimilar study submission may be kindly considered and our quoted product declare responsive.

Decision:

Mr. Zahid presented the above-mentioned grievance before the Grievance Redressal Committee on behalf of firm. The committee observed that the TEC has disqualified T.E. 48 & 49 due to failure in clause (viii) of compulsory parameters. The firm failed to demonstrate that the claimed biosimilar study has been conducted under accredited labs required under clause (viii) of compulsory parameters. The committee upheld the decision of Technical Evaluation Committee.

ITEM NO. 04:

GRIEVANCE SUBMITTED BY M/S IPRAM INERNTATIONAL (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We are writing to express our grievance regarding the technical evaluation report for the afore mentioned tender. Specifically, our quoted product T.E # 84 Injection Meropenem 500mg was not considered for the bid due to a typographical mistake in the T.E #. The following items were offered in our technical proposal (Page # 141).

- 1. T.E# 63 Imipenem + Cilastatin 500mg
- 2. T.E#84 Meropenem Injection 500mg

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Due to a typographical error, the T.E # for Injection Meropenem 500mg was incorrectly listed as T.E # 329 instead of T.E # 84. This mistake resulted in our quoted product Inj. Meropenem 500mg not being considered in the Technical Evaluation. Furthermore, we have attached all documents for Injection Meropenem 500mg as per requirement of Tender.

Therefore, we respectfully request that you accept our grievance and consider/include T.E # 84 Inj. Meropenem 500mg our quoted product in the bid and as responsive item.

Decision:

Mr. Sheikh Nauman, Sales Representative of firm presented the abovementioned grievance before the Grievance Redressal Committee. The firm presented the above-mentioned grievance.

Compulsory Parameters:

The committee observed that the firm has mentioned Inj. Meropenem 500mg but has mentioned T.E. 329 instead of 84. The committee accepted the grievance to this extent.

Ordinary Parameters:

The committee further observed that TEC has not graded the item in ordinary parameters. The committee checked the e-bid and declared firm responsive in compulsory parameters. The committee also graded T.E. 84 in ordinary parameters and awarded 5 marks in section (1) of marking criteria; 10 marks in section (2) of marking criteria; 10 marks in section (3); 10 marks in section (4); 9 marks in section (5); 5 marks in section (6); 6 marks in section (7); 2 marks in section (10); & 4 marks in section (11) of marking criteria.

The Inj. Meropenem 500mg quoted by the firm stands responsive in ordinary and compulsory parameters for T.E. 84.

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ITEM NO. 05:

Decision:

GRIEVANCE SUBMITTED BY M/S ENGLISH PHARMACEUTICAL INDUSTRIES (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

It is humbly stated that M/S English pharmaceuticals industries was technically non-graded in tender for bulk purchase of medicine 2025-26 though we are technically graded in all teaching hospital including services hospital Lahore, Lahore general hospital Lahore children hospital Lahore, children hospital Multan etc.. For same item that is inj. Vitamin K 1 quoted in this hospital. Sir, we were not given marks of public sector though we are supplying the same product in major hospital of Punjab we are attaching sale summary of these hospital along with supply order and DC's of these product with our request. Secondly we were only given 03 marks of credibility & certification manufacturer parameter though we have attached ISO 14001 and waste water treatment plant SOP these documents are once again attached with our letter. We were also not given marks of stability studies both acceleration and real time stability studies of quoted products are once again attached for reference. We were also not given marks of chain pharmacy invoices these invoices are once again attached our request letter.

It is requested to kindly consider these documents and technically graded our firm for next process so that we can serve public with quality product.

Mr. Usman, distributor of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified bid due to failure in clause (1) of compulsory parameters and less marks in ordinary parameters. The firm did not challenge the decision of TEC in section (1) of compulsory parameters and also did not attach copy of CDR with the grievance letter.

The firm remained non-responsive.

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ITEM NO. 06:

GRIEVANCE SUBMITTED BY M/S KAIZEN PHARMACEUTICALS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We are writing to bring to your kind attention a grievance regarding the submission of technical documents for the ongoing procurement process at your esteemed institution. Due to unforeseen circumstances, we are unable to submit certain required technical documents within the stipulated timeframe. We sincerely regret this and assure you that it was never our intention to overlook the process. In view of the above, we humbly request you to allow us an opportunity to submit the pending technical documents for your evaluation and consideration. We are fully prepared to comply with all required specifications and formats as per your institution's norms. We greatly value our association with Mayo Hospital and remain committed to maintaining the highest standards of quality and transparency in our offering. Your kind consideration of the requests will be deeply appreciated.

Decision:

Mr. Kamran, Institutional Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified bid due to failure in clause (1) of compulsory parameters and less marks in ordinary parameters. The firm did not challenge the decision of TEC in section (1) of compulsory parameters and also did not attach copy of CDR with the grievance letter. The firm remained non-responsive.

ITEM NO. 07:

GRIEVANCE SUBMITTED BY M/S BROOKES PHARMA (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

With reference to the technical evaluation report published for the financial year 2025-26 for the procurement of Drug / Medicine (SML). We would like to bring into your kind notice that your honorable technical committee of this esteemed hospital has declared the M/s. Bajwa Pharma as Responsive against the Item # 15 (Inj. Atracurium Besylate 5ml). In that regard, we would like to show our concern that these are highly sensitive drugs used in

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Anesthesia; low quality may lead to the serious life threat of the patient. Keeping the following aspects in view, it is requested to please review your decision".

Brookes Pharma fulfills the Technical & Quality parameters far more than other competitors. Enclosing the Sub-standard / Adulterated DTL report of Bajwa's Product & Grievance Minutes / result by one of the valued Institute / Department in Punjab, where Bajwa Pharma is disqualified due to false statement in Affidavit. As per our best knowledge, these competitor company has very much less Production Experience as well as very less Marketing Experience. Competitor company have not enough Past Experience regarding the supply of said product to Teaching Hospitals / Institutes in Punjab. Based on the quality of Product, competitor company have no appropriate End User Acceptance & have not enough confidence regarding their efficacy.

Whereas, Brookes Pharma Quality based Medicine: Brookes Pharma's products are standardized products due to quality, efficacy & efficiency within shelf lives. Brookes has vast End User Acceptance / Satisfaction due to its Quality of APIs as well as vast experience in supplying of those Items in Teaching Institutes in Punjab & throughout Pakistan. Availability of Standard Analytical Reports from DTL's Punjab: No batch "Misbranded /Substandard /Adulterated/ Spurious" declared any competent lab in PAKISTAN. Standard analytical reports available from International Lab for said Brand "Inj. Acuron (Atracurium Besylate). Experience with Mayo Hospital: Brookes Pharma also has vast experience supplying the said product for the last many years to your esteemed Hospital as well as last financial year.

In the light of the above details, we request to your respected committee to re-evaluate this technical report and re-consider the responsive status of M/s. Bajwa Pharma for the product Item# 15 (Inj. Atracurium Besylate 5ml) under the quality & technical grounds. We believe that only products meeting the highest quality benchmarks should be used in sensitive medical

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environments, and such re-evaluation will help ensure patient safety and procedural reliability. We hope the committee will treat this request with urgency and objectivity. Please confirm the initiation of this quality re-evaluation process and share the outcomes when available..

Decision:

Mr. Khalid, Institutional Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. Mr. Sultan Mahmood, Zonal Sales Manager defended the case on behalf of M/S Bajwa Pharmaceuticals. The petitioner presented the above-mentioned grievance but did not provide an iota of evidence to prove violation of any of the clauses of evaluation criteria and the ToRs of the bidding document. The committee regretted the grievance.

ITEM NO. 08:

GRIEVANCE SUBMITTED BY M/S GENIX PHARMA (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

Reference Technical Evaluation Report regarding our product Imipenem + Cilastatin Inj.500mg required with Water for Injection (Individual Pack). We are agreed to supply the below mentioned products with water for injection against non-responsive on following results;

Sr.	Generic Name	Brand Name	Documents Attached / Remarks
63	Imipenem + Cilastatin	Cilenem	Imipenem + Cilastatin Inj.500mg with
		injection	Water for Injection (Individual Pack)
		500mg	Samples are also providing.

Therefore we request you to declare us as responsive bidder to ensure healthy competition between bidders in procurement of medicine.

Decision:

Mr. Faisal Masud, Area Sales Manager of firm presented the abovementioned grievance before the Grievance Redressal Committee. The committee observed that the firm has not quoted solvent in the bid. The committee decided to uphold the decision of Technical Evaluation Committee.

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ITEM NO. 9:

GRIEVANCE SUBMITTED BY M/S LUCKY CORE INDUSTRIES (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

It is to inform you that we have participated in the tender for the procurement of drugs/medicines for the year 2025–2026. We would like to bring to your kind attention that Inj. Meropenem 500mg (Inj. Merpen 500mg) was inadvertently quoted under Tender Enquiry No. 80 instead of the correct Tender Enquiry No. 84, due to a typographical error. Whereas all the specifications quoted in the technical and financial proposal are correct and according to the requirement of the bidding documents.

In light of this, you are humbly requested to kindly consider Tender Enquiry No. 84 as the intended reference for Inj. Meropenem 500mg (Inj. Merpen 500mg), and to declare our bid as responsive against the said item..

Decision:

Mr. Tariq, Distributor of the firm presented the above-mentioned grievance before the Grievance Redressal Committee.

Compulsory Parameters:

The committee observed that the firm has mentioned Inj. Meropenem 500mg but has mentioned T.E. 80 instead of 84. The committee accepted the grievance to this extent.

Ordinary Parameters:

The committee observed that the TEC has not graded this item in ordinary parameters. The committee also graded T.E. 84 in ordinary parameters and awarded 5 marks in section (1) of marking criteria; 10 marks in section (2); 10 marks in section (3); insufficient public experience in section (4); 15 marks in section (5); 5 in section (6); 4 marks in section (7); 5 marks in section (10).

In conclusion the Inj. Merpen 500mg quoted by firm stands responsive under T.E. 84.

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ITEM NO. 10:

GRIEVANCE SUBMITTED BY M/S B.BRAUN PAKISTAN (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

With Reference to Technical Evaluation Report for above mentioned subject Our Below Products declared "Not Qualified" due to below reasons, Sir, please accept our grievance / Answers for the given Reasons in Remarks column of PQ Evaluation Report,

SR: No(06): Aminoacid 5% Inf. Compulsory parameter Non Responsive

SR: No. (80): Fat Emusion Inf. 20% Vial of 250ML - Compulsory & Ordinary parameter Non Responsive

SR: No. (89): Modified Fluid Gelatin - SR: No. Compulsory parameter Non-Responsive

Reason:1 Quality Compliance Standards (EMA/JMHLW/US FDA/prequalified by WHO (Certificate) of quoted item not attached.

Justification: Dear Sir, as you know EMA (European Medicines Agency)
Certified Company can be verified through its GMP. We are German Based
Company so, our German GMP can be check & Verify our attached GMP on
EMA Website. Link is as below

https://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do

Certificate & Screenshot of verification is attached. Please Consider and accept.

Reason: 2 Sales Summary Not Attached

Justification: Sir, we have provided / Attached sales summary please re consider

Sir, considering above facts it is requested to please re-consider and Re-Evaluate the Decision.

Decision:

Mr. kashif, Senior Product Specialist of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The firm claimed that it has been authorized by the European Medicine Agency. The committee observed that the firm has attached Certificate of GMP Compliance of

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Manufacturer that does not depict the EMA approval of finished products. The committee then accessed the list of EMA approved drug products through EMA site and found that the quoted products were not listed in EMA approved drugs. The committee upheld the decision of Technical Evaluation Committee.

ITEM NO. 11:

GRIEVANCE SUBMITTED BY M/S BF BIOSCIENCES (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We respectfully submit our grievance regarding the technical evaluation of the above-mentioned tender. Our product, Eritrogen 4000IU Injection, was disqualified based on the reason cited as "Non-provision of bio-similarity studies from DRAP-notified labs or WHO/FDA/EMA accredited labs", as stipulated in Clause 8 of the Compulsory Parameters. We would like to clarify that the complete bio-similarity study report for Eritrogen 4000IU was submitted along with the bid. These same studies were reviewed and accepted by DRAP, based on which DRAP granted us registration for Eritrogen 4000IU as a Biological Drug. We filed our registration application in accordance with the guidelines approved by the DRAP Registration Board during its 278th meeting held from January 29th - 31st, 2018. Subsequently, in the 288th meeting held on February 14th-15th, 2019, the Board approved our product after being satisfied with the submitted data and documentation. (Copies of the meeting minutes are attached for your reference.) Furthermore, Eritrogen 4000IU has been consistently supplied to your esteemed hospitals for several years without any reported complaints. Copies of relevant award letters are enclosed as proof of our track record. It is important to highlight that Eritrogen 4000 IU/PFS was prequalified in the prequalification of D.G.H.S. Punjab 2024-25, and also in the current financial year (2025-26), our product has been technically approved under similar evaluation criteria at various institutions within the Specialized Healthcare Department, including:

Services Hospital, Lahore

Lahore General Hospital, Lahore

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- Children's Hospital Lahore
- Sahiwal Teaching Hospital, Sahiwal
- Sheikh Zayed Hospital, Rahim Yar Khan
- Allama Iqbal Teaching Hospital, D.G. Khan
- Nishtar Hospital, Multan
- Khawaja Muhammad Safdar Medical College & Allied Institutions, Sialkot.
- Govt Main Munshi Hospital Lahore.
- Gujranwala Teaching Hospital, + Gujranwala.

Technical evaluation reports from these institutions are enclosed for your kind review. n light of the above, we earnestly request you to reconsider the technical disqualification of Eritrogen 4000IU and declare our bid Responsive, thereby allowing us to participate in the next phase of financial bidding.

We respectfully submit our grievance concerning the technical evaluation of the annual framework contract for bulk drug procurement (FY 2025-26), specifically regarding the evaluation of the following AJM Pharma for T.E. 51 Inj. Erythropoietin alfa (4000 IU) Prefilled Inj. EPIAO 4000 IU. It is important to note that the quoted brand does not meet the mandatory quality parameters required for the bid, particularly those applicable to Sole Agents/Importers of Foreign Principals. The key deficiencies are as follows:

Our Grievance: The quoted product, EPIAO 4000 IU, fails to meet the mandatory quality compliance standards and has been disqualified in DGHS Annual Tender Sr. No. 1, Bid Inquiry 30 (2025-26) due to the following reasons: (TE Report Page Enclosed)

- 1. The attached bio similarity study was not conducted by DRAP-notified labs, WHO/EMA/JPHMLW.
- 2. The bidder's name is not mentioned on the submitted samples; instead, AA Pharma is noted as the importer/Distributor.
- 3. The GMP/COPP of the manufacturer has not been verified. While verification through the QR code opens up different documents. Further, the GMP certificate is provided in the Chinese language, and upon its

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translation, it indicates that it is a GMP Inspection report rather than a GMP certificate.

 Quality Compliance Standards (EMA/ JMHLW/ US FDA/ prequalified by WHO of quoted item not attached. 2.ISO 9001 of the bidder is not attached.

Moreover, the same product was also disqualified in the DGHS Annual Prequalification 2024-25 for not meeting the required standards. Additionally, adequate documentation was not presented during the Grievance Redressal meeting (refer to the attached Technical Evaluation Report and Committee Minutes). Furthermore, we have enclosed herewith the letter from Mayo Hospital Lahore to The Managing Director PPRA S&GAD Lahore, Punjab. He checked "the online resources for biosimilar studies approved from US FDA/WHO/FDA/EMA/JPMHLW and approval of quoted product from US FDA/WHO/FDA/EMA/JPMHLW and was unable to find the approval of T.E 9 EPIAO 4000 IU quoted by AA Pharma from mentioned authorities as required under clauses x & xi of compulsory parameters. (Letter enclosed).

We believe adherence to quality standards is vital for public interest, optimal fund utilization, and stakeholder value. We respectfully request that the Grievance Redressal Committee review their observations and uphold the bid's quality criteria.

We respectfully submit our grievance regarding the technical evaluation of the above-mentioned tender. Our product, Noxane 40mg and Noxane 60mg, was disqualified based on the reason cited as "Non-provision of biosimilarity studies from DRAP-notified labs or WHO/FDA/EMA accredited labs", as stipulated in Clause 8 of the Compulsory Parameters. We would like to clarify that the complete bio-similarity study report for Enoxaparin Sodium "Noxane" was submitted along with the bid. These same studies were reviewed and accepted by DRAP, based on which DRAP granted us registration as a Biological Drug. We filed our registration application in

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accordance with the guidelines approved by the DRAP Registration Board during its 278th meeting held from January 29th - 31st, 2018. Subsequently, the Board approved our product after being satisfied with the submitted data and documentation. Furthermore, Noxane has been consistently supplied to your esteemed hospitals for several years without any reported complaints. Copies of relevant award letters are enclosed as proof of our track record.

It is also important to highlight that in the current financial year (2025–26), our product has been technically approved under similar evaluation criteria at various institutions within the Specialized Healthcare Department, including:

- Services Hospital, Lahore
- Sahiwal Teaching Hospital, Sahiwal
- Sheikh Zayed Hospital, Rahim Yar Khan
- Allama Iqbal Teaching Hospital, D.G. Khan
- Nishtar Hospital, Multan
- Gujranwala Teaching Hospital (DHQ) Gujranwala
- Holy Family Hospital Rawalpindi
- Benazir Bhutto Hospital Rawalpindi
- **CPEIC Multan**
- Govt Kot Khawaja Saeed Teaching Hospital Lahore

Technical evaluation reports from these institutions are enclosed for your kind review.

In light of the above, we earnestly request you to reconsider the technical disqualification of Noxane 40mg, 60mg, and declare our bid Responsive, thereby allowing us to participate in the next phase of financial bidding.

Decision:

Mr. Saeed, Senior Sales Engineer of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified T.E. 48, 49 & 51 as the Biosimilar studies have not been conducted by the labs notified by regulatory authorities required under section (viii) of compulsory parameters. The firm could not provide the Biosimilar studies as per

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requirement of instant clause due to which the committee upheld the decision of TEC.

Grievance against M/S AJM

Mr. Saeed Sales Manager of M/S AJM defended the case on behalf of AJM. The committee also discussed the grievance against M/S AJM Pharma. The committee observed that T.E. 51 quoted by AJM is already non-responsive in section (vii) & (viii) of compulsory parameters.

ITEM NO. 12:

GRIEVANCE SUBMITTED BY M/S HOECHST PAKISTAN (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

This grievance application is being submitted under Rule 67(2) of the Punjab Procurement Rules, 2014 (PPRA Rules), in reference to the Technical Evaluation Report for the Tender regarding the Purchase of Drugs and Medicines for the year 2025–26. We respectfully bring the following concerns to your kind attention for review:

Non-Provision of Samples for Quoted Products (Sr. #1799 – Lasoride Tablet & Sr. #194 – Neodipar Tablet):

We wish to clarify that the product samples were dispatched from our head office via courier; however, the courier service could not deliver them within the stipulated time. Despite our immediate efforts to submit the samples upon arrival, the institution declined to accept them post-deadline.

We are now submitting the samples along with this grievance and humbly request that they be considered valid for evaluation as these are well experienced medicines already in use.

Low Marks in Public & Private Sector Experience (Sr. #23 – Claforan Injection, Sr. #25 – Aventriax Injection, Sr. #182 – Amaryl Tablet):

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We have been awarded lower marks under the Public & Private Sector Experience criterion, despite having submitted Purchase Orders (POs), Delivery Challans (DCs), and a comprehensive summary with our bid.

With this grievance, we are attaching additional POs and supporting documents to further substantiate our claim. We respectfully request a reevaluation and revision of the awarded marks in light of this documentation.

Non-Consideration of FDA Approval (Sr. #47 – No-Spa Injection & Sr. #182 – Amaryl Tablet):

We have provided FDA approval certificates for the above-mentioned products with our bid. However, these approvals were not considered in the evaluation. We request a review of these documents and inclusion of the respective marks. Amaryl FDA LINK https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Regarding NO Spa Injection it is not marketed in USA so it has no FDA Approval, but it's being used in all Europe and Pakistan from Many Years as research Product of Hoechst, so please approve this Product as per need of Patients.

In light of the above, we humbly request a review of the Technical Evaluation Report and that our quoted products be re-evaluated and declared responsive accordingly In light of the above, we earnestly request you to reconsider the technical disqualification of Noxane 40mg, 60mg, and declare our bid Responsive, thereby allowing us to participate in the next phase of financial bidding.

Decision:

Mr. Sajid, distributor of the firm presented the above-mentioned grievance before the Grievance Redressal Committee. The firm stated that Technical Evaluation Committee has disqualified T.E. 179 & 194 in clause (vi) of compulsory parameters due to non-provision of samples, while T.E. 47 and 182 has been disapproved due to failure in clause (vii) of compulsory

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parameters. The TEC has also disapproved T.E. 23, 25 & 182 due to less marks in marking criteria.

Compulsory Parameters:

The firm provided samples for T.E. 179 & 194 that were found as per advertised specs and stands responsive in clause 6 & 10 of compulsory parameters. The firm also could not provide necessary documents to prove requirement of clause (vii) of compulsory parameters for T.E. 47 that also remained non-responsive. The firm showed approval of T.E. 182 in FDA Orange Book and the item stands responsive in clause (vii) of compulsory parameters.

Ordinary Parameters:

However, the firm showed approval of T.E. 182 in FDA orange book. The committee also awarded 5 marks in section (vi) of ordinary parameters.

In conclusion T.E. 179, 194 & 182 stands responsive in compulsory as well as ordinary parameters.

ITEM NO. 13:

GRIEVANCE SUBMITTED BY M/S AJ MIRZA PHARMA (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

With due respect, we submit this grievance regarding our disqualification in the technical evaluation of the above-referenced tender. We had quoted our product under T.E No. 51 – Erythropoietin 4000 IU Injection PFS & T.E# 111 Inj. Lung Surfactant, and have been disqualified under the following criteria. We would like to clarify each point below:

T.E # 51 Erythropoietin 4000 IU Injection PFS

Clause # VIII— Biosimilar Study: Our biosimilar study was conducted at North Western Eastern University, a WHO-prequalified university in Russia. We are attaching the supporting reference documents to establish the credibility and compliance of the study. Our biosimilar studies were conducted in accordance with the guidelines of the European Medicines Agency (EMA),

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using Eprex (the innovator brand) as the reference product. Moreover, biosimilar study is published on the official NIH-US website. https://pubmed.ncbi.nlm.nih.gov/36451454/, being regulated under USFDA guidelines. This ensures that the development and comparability assessment meet internationally recognized standards for biosimilarity.

Clause#VII: Quality Compliance Standards, we are complying with the requirements. Certificate issued by USFDA is attached in bid and here again. The product is also registered in multiple countries, including with ANVISA (Brazil's Health Regulatory Agency). Furthermore, ANVISA and US FDA have signed a Mutual Statement of Cooperation, recognizing shared standards and compliance. A copy of this statement and the GMP issued by Brazil is attached, further validating that our product meets US FDA-level standards.

It is also pertinent to mention that Prequalification clause only requires compliance to international standard i.e US FDA/ EMA JPMHLW and in case WHO Prequalified certificate is required only. Therefore, perusal of registration in Brazil, attached GMP issued by Brazil clearly establishes that standards of US FDA are duly met in the light of Statement of Cooperation signed between US FDA and ANVISA Brazil.

Sample Not approved: We would like to clarify that the samples submitted with the tender were from an earlier batch when the product was registered under AA Pharma as the importer/distributor.

At the time of submission, we were in the process of transferring the product registration to A.J. Mirza Pharma (Pvt) Ltd, and therefore, fresh stock under the new registration was not yet available. We had submitted a letter explaining this situation prior to the technical committee's review.

Please note that there is no change in the manufacturer or product specifications—only the name of the importer has changed. The new import under A.J. Mirza Pharma is currently in process.

T.E# 111 Inj. Lung Surfactant.

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Clause#7: We have submitted EDQM certificate with the bid. The European Medicines Agency (EMA) works with the European Directorate for the Quality of Medicines and HealthCare (EDQM), a directorate of the Council of Europe. The EMA and the EDQM cooperate on matters aimed at ensuring the quality of medicines and protection of public health. You are requested to accept.

Moreover, it is registered in for PIC/s countries, The Pharmaceutical Inspection Co-operation Scheme (PIC/S). PIC is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use.

Against M/S Cheisi Pharma.

We would like to bring to your attention that M/S Chiesi Pharma has quoted Inj. Curosurf, which is derived from a porcine (pig) source. In contrast, other available brand is with a bovine (cow) source, which is considered halal and more acceptable for human use, especially in our region. We have strong reason to believe that their submitted biosimilar studies were not conducted in a USFDA-approved, WHO-accredited, or DRAP-notified laboratory.

Decision:

Mr. M. Saeed, Sales Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified T.E. 51 due to failure in section (vii) & (viii) of compulsory parameters and T.E. 111 due to failure in (vii) of compulsory parameters. The committee accessed the WHO prequalified labs through https://extranet.who.int/prequal/medicines/prequalified/quality-control-labs and found that the said study has not been say devoted form the lines.

labs and found that the said study has not been conducted from the listed prequalified labs. The committee also accessed the list of EMA approved drugs and found that T.E# 51 & 111 Inj. Lung Surfactant are not listed in it.

The committee upheld the decision of Technical Evaluation Committee.

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Grievance against M/S Cheisi Pharma

The petitioner stated that the said item does not have biosimilar studies provided under clause () of compulsory parameters. The committee observed that the firm has not attached any documents pertaining to biosimilar studies. The committee also accessed the data on FDA at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process where Curosurf RLD (Reference Listed Drug) was 'no'. The committee decided to declare T.E. 111 quoted by M/S Chiesi Pharma disqualified in clause (viii) of compulsory parameters.

ITEM NO. 14:

GRIEVANCE SUBMITTED BY M/S OTSUKA PAKISTAN (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We Otsuka Pakistan Limited is writing to express our grievance against the nominated Non-Responsive status for subject mentioned serials as in technical evaluation report of bulk purchase of medicine/injectable for year 2025-2026 uploaded by your worthy institute on E-PADS. We have submitted the bid and had fulfilled all the eligibility criteria and tender requirements as specified in tender documents but our experience of public and private sector was not considered in Technical evaluation report for subject mentioned products. We request you to re-consider our bid and take necessary actions to rectify this situation. Kindly consider the subject mentioned request and oblige.

Decision:

Mr. Younus, Institutional Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified bid due to failure in ordinary parameters i.e. 31 for T.E. 6 and 25 for T.E 80. The committee observed that the TEC has also disqualified T.E. 80 due to clause (iv) of compulsory parameters for which the firm has not challenged. The TEC decision for T.E. 80 remained unchanged. The committee also observed that the firm has provided an undertaking regarding experience in Public institutions that has been established after date of tender opening — hence

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regretted. The committee upheld the decision of Technical Evaluation Committee.

ITEM NO. 15:

GRIEVANCE DETAIL:

GRIEVANCE SUBMITTED BY M/S HAKIMSON IMPEX (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

We would like to clarify the disqualification of our product, Snake Venom Antiserum, from the Mayo Hospital, Lahore tender for FY 2025–2026. The stated reason was that the product is neither WHO-prequalified nor approved by any Stringent Regulatory Authority (SRA). Please consider the following points in support of our product:

- 1. The Snake species found in India, Pakistan, Sri Lanka, Myanmar, Afghanistan, Nepal and Bangladesh are not found in any of the SRA countries, which is why this product is not registered in any of those countries The product coming to Pakistan is pertinent only to the regional species of snakes, and as such is not available in any of the SRA countries. (Letter of Bharat Serum & Vaccine is attached).
- 2. Central Drugs Standard Control Organization: Central Drug Laboratory, Kasauli (India), which is a WHO pre-qualified lab, gives the Lot release for every lot exported. On the Basis of the lot release from Kasauli, the NCL in Islamabad gives a lot release.
- Bharat Serum & Vaccine Limited's company name is included in the list of WHO-recognized manufacturers of anti-snake venom (WHO Guidelines Management of snake bites
- 4. Attached are previous order copies of ASVS supplied by Bharat Serum and Vaccine India to the WHO
- 5. Bharat Serum and Vaccine is an ISO (9001,14001, and 45001) Certified company

In light of the clarifications and evidence submitted, we ask that our product be re-evaluated accordingly.

Decision:

Mr. Tayyab, Institutional Manager of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee

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observed that Technical Evaluation Committee has disqualified T.E. 13 due to failure in section (vii) of compulsory parameters. The firm failed to provide WHO approval/ prequalification of T.E. 13. The committee upheld the decision of Technical Evaluation Committee.

ITEM NO. 16:

GRIEVANCE SUBMITTED BY M/S BAJWA PHARMACUETICALS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We respectfully bring to your attention serious concerns regarding the participation of M/S Brookes Pharma in the current tender process. Please find enclosed the Drug Testing Laboratory (DTL) Report issued from Faisalabad vide TRA No. 01-68029445 dated March 26, 2024, pertaining to Batch No. 08913, which has been declared Fail – Spurious. In this regard, it is pertinent to highlight that as per the bidding documents, under Clause No. 9(a) & 9(b) (page 37-38) of the compulsory parameters: Clause 9: The firm shall submit an undertaking on Rs.100/- stamp paper, duly legalized/notarized, confirming that:

- a) None of its supplied batches in the Private or Public Sector has been declared Spurious / Adulterated by DTLs of Punjab or any competent laboratory during the last three years up to the closing date of bid submission.
- b) There has been no declaration of any Spurious / Adulterated batch of the quoted item manufactured by the firm by DTLs of Punjab or any competent laboratory.

Given the above findings, it is evident that M/s Brookes Pharma does not fulfill the compulsory eligibility criteria outlined in the tender documents. We therefore request your kind office to take immediate corrective action by disqualifying M/s Brookes Pharma from further participation in the bidding process, in the interest of transparency and patient safety.

Decision:

Mr. Sultan Mehmood Zonal Sales Manager of the firm presented the abovementioned grievance before the Grievance Redressal Committee. Mr. Khalid

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defended the case on behalf of M/S Brookes Pharma. The petitioner presented the above-mentioned grievance. The committee requested the petitioner to present the bill warranty of said Batch to demonstrate that the said item has been manufactured by M/S Brookes Pharma. The petitioner did not have any single document to confirm that the controversial spurious product has been manufactured by the defendant. The committee regretted the grievance.

ITEM NO. 17:

GRIEVANCE SUBMITTED BY M/S SYNCHRO PHARMACUETICALS (PROCUREMENT OF DRUGS/ MEDICINES SML 2025-26 MAYO HOSPITAL, LAHORE)

GRIEVANCE DETAIL:

We have come to know through uploaded Evaluation report for the tender framework contract for Drugs/Medicine for the financial year 2025-2026. In this regard we want to draw your attention that our firm is non-responsive due to non-provision of documents. We have attached all the relevant documents with the technical bid which are essential for qualifying criteria. So, you are requested kindly look into the matter and our grievance may kindly be considered and allow us to re-submit the same and obliged.

Decision:

Mr. Usman, distributor of firm presented the above-mentioned grievance before the Grievance Redressal Committee. The committee observed that Technical Evaluation Committee has disqualified bid due to failure in ordinary parameters.

Ordinary Parameters: Public Experience

The firm alleged that the TEC has disqualified firm due to non-provision of documents, but the committee observed that the TEC has graded the bid on different parameters. The committee observed that the firm has attached public experience from pages 326 to 348 and did not contain delivery challans. The firm attached summary of public experience on an undertaking that did not mention details of T.E. 22, 23, 25, 169, 204, 208 & 152. The firm showed DCs for T.E. 72 and scored 3 marks in section 4. The POs & corresponding DCs for T.E. 100, 151, 153 for past two years were not

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provided. The firm did not provide additional documents to claim marks in ordinary parameters. The committee upheld the decision of Technical **Evaluation Committee.**

The meeting ended with vote of thanks to and by the Chair.

Mr. Muhammad Jawad Bhatti **Deputy Drugs Controller**

Mayo Hospital Lahore

MS. Kanwal Javed Deputy Drugs Controller

Mayo Hospital Lahore

Assistant Profesor Plastic Surgery

Mayo Hospital Lahore

Dr. Rabia Rathore

Associate Professor of Medicine/Head of WMW Mayo Hospital Lahore

Rabia Rathore.

Dr./Nasi/ Chaudhary HoD Ophthalmology Department

Mayo Hospital Lahore

COO! As per decisions of committee.

AMS(P) Upland as per Rules

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