MINUTES OF GRIEVANCES MEETING

MAYO HOSPITAL LAHORE

Participants:

1.	**Prof. Dr. Nasir Chaudhary** *Head of Ophthalmology Department Unit-II Mayo Hospital Lahore*	**Chairman**
2.	**Dr. Umar Nazir** *Assistant Professor of Plastic Surgery Mayo Hospital Lahore*	**Member**
3.	**Dr. Sana Farooq** *Senior Registrar Neurology Department Mayo Hospital Lahore*	**Member**
4.	**Mr. Azeem Butt** *Deputy Drugs Controller Mayo Hospital Lahore*	**Member**
5.	**Mr. Muhammad Jawad Bhatti** *Deputy Drugs Controller Mayo Hospital Lahore*	**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 KOHINOOR INDUSTRIES (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance that the firm has been declared non responsive due to missing documents against T.E. 209. Povidonelodine10% Solution 450ml & T.E. 210 Povidonelodine7.5% 450ml. The firm claimed to attach Source of API of Quoted Items, Experience of the quoted products (private & public Sectors), (B,C,D) Credibility & Certification of Manufacturer (ISO14001, Int. Reputed Certificate, Waste Water Treatment Plant), Stability Study, Primary Reference Standard with valid shelf life used for QC & List of Technical Staff with Appointment Letters.

Decision: Mr. Arif Institutional Sales Officer of M/S Kohinoor Industries pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for all quoted items due to failure in Marking Criteria. The firm's representative stated that the firm has sufficient experience to claim 20 marks for T.E. 209 in Section 3 & 4 of Marking Criteria. The firm provided an undertaking stating that the firm has supplied 5400 bottles in private sector and 4400 bottles in public sector.

He further showed Sales Invoice No. 01-10-378 dated 12.03.2023 to supply 500 bottles to M/S Servaid Pharmacy Lahore, Sales Invoice No. 06-18-309 dated 11.11.2022 to supply 400 bottles to M/S Servaid Pharmacy Lahore, Sales Invoice No. 06-25-22 dated 02.09.2022 to supply 300 bottles to M/S Servaid Pharmacy Lahore, Sales Invoice No. 06-18-314 dated 26.12.2022 to supply 500 bottles to M/S Fazal Din Pharma Plus Lahore, Sales Invoice No. 214 dated 05.08.2023 to supply 200 bottles to M/S Mian Enterprises, Sales Invoice No. 211 dated 05.08.2023 to supply 900 bottles to M/S Geo Health Pakistan Rawalpindi, Sales Invoice No. 191 dated 03.08.2023 to supply 400 bottles to M/S Madina Medicine Company Multan, Sales Invoice No. 70 dated 11.07.2023 to supply 1000 bottles to M/S Al-Saad Enterprises Peshawar, Sales Invoice No. 9 dated 11.07.2023 to supply 400 bottles to M/S Haroon Enterprises Peshawar. **The committee awarded 10 marks to T.E 209 in section 3 of Marking Criteria**. The firm's representative then claimed that the firm has sufficient experience to claim 10 marks for T.E. 209 in Section 4 of Marking Criteria. The firm provided PO No. 62166 dated 16.10.2023 for 6000 bottles including DC No. 55693 to supply 2820 bottles and DC No. 55697 to supply 3180 bottles to Children Hospital Lahore. **The committee awarded 10 marks to T.E. 209 in section 4 of Marking Criteria.**

The firm's representative stated that the firm has sufficient experience to claim 20 marks for T.E. 210 in Section 3 & 4 of Marking Criteria. The firm showed an undertaking stating that the firm has supplied 3800 bottles in private sector and 3200 bottles in public sector. He further showed Sales Invoice No. 01-10-308 dated 15.04.2023 to supply 400 bottles to Fazal Din Pharma Plus Lahore, Sales Invoice No. 01-10-378 dated 12.03.2023 to supply 400 bottles to Servaid Pharmacy Lahore, Sales Invoice No. 06-18-309 dated 11.01.2022 to supply 200 bottles to Servaid Pharmacy Lahore, Sales Invoice No. 06-25-22 dated 02.09.2022 to supply 200 bottles to Servaid Pharmacy Lahore, Sales Invoice No. 06-18-314 dated 26.12.2022 to supply 200 bottles to Fazal Din Pharma Plus Lahore, Sales Invoice No. 01-10-485 dated 06.08.2022 to supply 800 bottles to Clinix Pharmacy Lahore, Sales Invoice No.

211 dated 05.08.2023 to supply 480 bottles to Geo Health Pakistan Rawalpindi, Sales Invoice No. 70 dated 11.07.2023 to supply 200 bottles to Al-Saad Enterprises Peshawar, Sales Invoice No. 369 dated 31.08.2023 to supply 220 bottles to Shazeb Pharma Rawalpindi. **The committee awarded 10 marks to T.E. 210 in section 3 of Marking Criteria.** The firm's representative then claimed that the firm has sufficient experience to claim 10 marks for T.E. 210 in Section 4 of Marking Criteria. The firm showed PO No. 62169/CH&UCHS dated 16.10.2023 for 6000 bottles & DC NO. 55695 to supply 4180 bottles & DC No. 55694 to supply 1820 bottles to Children Hospital Lahore. **The committee awarded 10 marks to T.E. 210 in section 4 of Marking Criteria.**

The firm then claimed 3 marks in section 5 (D) of Marking Criteria. The firm showed Waste Water Treatment SOP and layout plan. **The committee awarded 3 marks in section 5 (D) of marking criteria.**

The firm then claimed 2 marks for T.E. 210 in section 8 of marking criteria. The firm showed Realtime & Accelerated study data**. The committee awarded 2 marks in section 8 of marking criteria.**

The firm then claimed 2 marks in section 10 of Marking Criteria. The firm showed the details of 10 pharmacists including the appointment letters and copies of degrees. **The committee awarded 2 marks in section 10 of marking criteria.**

The committee decided to declare T.E. 209 & 210 responsive in Marking Criteria by achieving 50 marks.

ITEM NO. 02: **GRIEVANCE SUBMITTED BY M/S ALLMED PVT. LTD. (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance with reference to non-responsive status due to GMP Certificate not attached. The firm claimed that Original GMP was delayed due to inspection committee The tender Opening date was 03/05/2024 and Application renewal submission date was 24/04/2024 that has been attached in technical bid. The firm claimed that the delay is from

DRAP and the firm was not able to provide at the time of submission of bid date. The firm claimed to have attached Fresh Valid GMP from DRAP after Inspection satisfactory by DRAP.

Decision: Mr. Imran Baloch, Regional Sales Manager of M/S Allmed (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid due to failure in clause viii of Compulsory Parameters. The committee observed that the firm attached GMP certificate dated 05.07.2021 valid for 2 years. The request for renewal of GMP certificate was also in the bid. The firm provided renewed GMP Certificate **The committee decided to declare firm responsive in clause viii of Compulsory Parameters.**

ITEM NO. 03: **GRIEVANCE SUBMITTED BY M/S LAB DIAGNOSTIC SYSTEM PVT. LTD (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance that the firm has been evaluated with less than desired marks by the committee. Regarding compulsory parameters, the firm claimed that it is the authorized distributor and importer of quoted items for which valid copies of LOA from Principles are attached describing relationship with Principal for the last 5 years, DRCs, API GMP approved by WHO, biosimilar study is attached for TE: 43, 44, 52 being biological items while rest are exempted & samples of T.E. 43 & 44 shall be provided. Regarding ordinary parameters, the firm claimed to have attached the requested summary with detailed and arranged Purchase orders for sections 1 & 3. The firm also claimed to attach Authority letter from 2019 till 2023 different T.E items, and Export of TE 43, 44 and 52 to USA and other countries.

Decision: Mr. M. Sheraz, Area Business Manager of M/S Lab Diagnostic System (Pvt.) Ltd. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for due to failure in clause vii & ix for all quoted items & clause viii for T.E. 109, 196 & 206 and failure in marking criteria for all quoted items. The firm's representative showed a distribution certificate but failed to show the Sole

Agency Agreement and necessary documents to qualify Compulsory Parameters especially clauses vii & ix of Compulsory Parameters. **The committee decided to uphold the decision of Technical Evaluation Committee.**

ITEM NO. 04: **GRIEVANCE SUBMITTED BY M/S A.J. MIRZA (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance that firm got less marks in ordinary parameters. Regarding T.E # 81- Inj. Bortezomib 3.5mg (Bortesoh), the firm stated that it got 37 marks in ordinary parameters. For Clause# 3, Experience in public sector, the firm received zero marks, for which the firm is attaching sale confirmation in international market. For Clause # 8, Availability of quoted product where the firm has got zero marks, the firm has attached airway bill of USA, and submitting again. For T.E# 192 Tab Abirateron (Abirone), under Clause # 8, (ordinary Parameter)the firm got 1 mark, though it claims 10 marks as it has attached Airway bill of US. For T.E # 188 Tab Sorafenib 200mg (Soranib 200mg) under Clause # 1 & 3, (ordinary Parameter) TEC gave zero marks in experience though the firm claimed to have attached few POs and now attaching POs with DCs.

Decision: Mr. Marium, Senior Specialty Manager of M/S A.J. Mirza. pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for T.E. 81, 192 & 188 due to failure in marking criteria. The firm's representative claimed 10 marks in section 8 of Marking Criteria. The firm showed two Sea Way bills for shipment of Inj. Bortezomib to United States. **The committee decided to declare T.E. 81 responsive in marking criteria by achieving 47 marks.** The firm's representative then claimed 10 marks for T.E. 192 in section 8 of marking criteria. The firm showed Seaway bills for United States of America that could not be verified. The firm also claimed marks in section 1 of marking criteria. The committee observed that the firm has mentioned no experience in undertaking attached in the bid The committee decided to turn down grievance to the extent of T.E. 192 & 188.

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ITEM NO. 05: **GRIEVANCE SUBMITTED BY M/S A.A. PHARMA (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance that the firm has been disqualified in compulsory & ordinary parameters. Regarding Compulsory Parameter: Clause # xi, the firm claimed that its quoted product, Inj. Zefei, is an FDA-approved drug for which the ANDA report has already been attached with bid and attaching again for review. Regarding Ordinary parameters the TEC gave 43 marks though the firm has attached documents with the bid and submitting again. Regarding Clause# 3, experience in public sector the TEC gave zero marks in this clause for which the firm claimed to have attached the Purchase Orders (PO) with Delivery Challan (DC). Regarding Clause# 6, Compliance of Quality Standard, TEC gave zero marks though the product is FDA approved. Regarding Clause # 8, Availability of quoted product, TEC gave zero marks, while the firm claimed to have attached airway bill of USA. The firm added that it could not submit sample for T.E. 49 due to shortage of stock and import issue.

Decision: Mr. Marium, Senior Specialty Manager of M/S A.A. Pharma pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for TE No. 46 due to failure in clause (xi), T.E. 49 due to failure in clause 2: Evaluation of Samples and T.E. 46, 48 & 49 due to failure in marking criteria. The firm's representative stated that it could not provide samples due to import issues and provided sample for T.E. 49 that was found as per advertised specs and was declared responsive in clause 2: Evaluation of Sample. The firm further claimed that its quoted products T.E. 48 & 49 are USFDA approved and listed in FDA Approved Drug Products. The committee awarded 5 marks to T.E. 48 & 49 in section 6 of marking criteria. **The committee decided to declare T.E. 48 responsive in clause 2: Evaluation of Samples and T.E. 48 & 49 responsive in marking criteria by achieving 48 marks respectively.**

ITEM NO. 06: **GRIEVANCE SUBMITTED BY M/S SAMI PHARMACEUTICALS (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

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GRIEVANCE DETAIL:

The firm submitted the grievance with reference to subject cited tender and claimed to submit requisite documents for consideration: Undertaking regarding non-declaration of spurious / adulterated batch dully notarized, Undertaking regarding firm has not been prosecuted by Provincial Quality Control Board PQCB dully notarized, Undertaking regarding firm not currently blacklisted by Mayo Hospital Lahore dully notarized, Undertaking regarding the supplies of stock in Reefer container dully notarized, Undertaking regarding the supply of stock in compliance to SRO 470 (I) /2017 dully notarized, Undertaking regarding the acceptance of terms and conditions as laid down in bidding documents dully notarized, Undertaking regarding the supply of stocks from the claimed API source dully notarized, Summary for supply of products in Public Sector on stamp paper of Rs.100/- dully notarized, Summary for supply of products in Private Sector on stamp paper of Rs.100/- dully notarized, Undertaking regarding declaration of no match declared substandard by DTL during last financial year dully notarized, Undertaking regarding availability of functional climatic/ stability chambers along with relevant annexures dully notarized, Layout plan for Waste water treatment plant along with relevant SOPs, Reference standard documents along with API documents for the quoted products , Copy of ISO/IEC 17025:2017, Copy Certificate issued from IQVIA showing the ranking of firm & Undertaking regarding technical staff along with relevant details

Decision:

Mr. Tayyub, Institutional Manager of M/S Sami Pharmaceuticals pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid due to failure in clause (xii), (xiv), (xv), (xvi), (xviii), (xix) of compulsory parameters and failure in marking criteria. The committee observed that the firm has not challenged the decision of TEC in clause (xii) against which the firm is also disqualified. **The committee decided to uphold the decision of Technical Evaluation Committee.**

ITEM NO. 07: **GRIEVANCE SUBMITTED BY M/S BROOKES PHARMACEUTICALS (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance with reference to TEC report that has declared Item# 87 – Inj. D-Cort 4mg/ml (Inj. Dexamethasone 4mg/ml) as non-Responsive because of non-submission of Tender Samples. The firm desired to submit Tender Samples of the above-mentioned quoted product for your kind consideration.

Decision: Mr. Khalid, Field Manager of M/S Brookes Pharmaceuticals pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for T.E. 87 due to failure in clause (ii) of compulsory parameters and failure in evaluation criteria. The committee observed that the firm has not challenged the decision of TEC in marking criteria for T.E. 87. **The committee decided to uphold the decision of Technical Evaluation Committee.**

ITEM NO. 08: **GRIEVANCE SUBMITTED BY M/S ROCHE PAKISTAN LTD. (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance regarding the product Trastuget 440 mg, which Getz Pharma is importing from Biocon, India. It is technically approved in the evaluation report issued by the authority. Bid inquiry no. 126.

The firm stated that as per compulsory parameters specified in the tender documents, Clause XI states that: The bidder is required to provide biosimilarity study data for the quoted item (applicable to biologicals and biotech products). The biosimilar study must be conducted by labs notified by DRAP or accredited by WHO/JpMHLW/EMA/US FDA. Alternatively, the quoted product must have the status of reference product for biosimilar studies by the US FDA/registered at EMA official website. The firm claimed that upon review, the biosimilarity study referenced in Getz Pharma's marketing materials pertains to the Heritage Trial Phase III, sponsored by Mylan GmbH for their brand-not specifically for Trastuget as claimed. The firm alleged that this raises concerns about the accuracy and compliance of the

submitted data. The firm claimed to attach documentation of the trial, clearly identifying Mylan GmbH as the responsible entity and funder of the study. - Clinical trial identification: EudraCT No: 2011-001965-42, - Legal entity responsible for the study: Mylan GmbH - Funding: Mylan GmbH.

The firm added that clause X of the compulsory parameter states that Quoted product must have WHO Prequalification/JpMHLW/EMA/USFDA approval. The firm claimed that, contrary to the claims made, publicly available information from the official websites of these regulatory bodies indicates that Trastuget 440 mg by Getz Pharma does not feature in the lists of approved biosimilars: FDA Biosimilar Trastuzumab 440 mg: https://purplebooksearch.fda.gov/results?query=trastuzumab&title=Herceptin. EMA Biosimilar Trastuzumab 440 mg: https://www.ema.europa.eu/en/search? search api fulltext-trastuzumab & f%5B0 %5D=ema search topics%3A45. WHO Prequalified Trastuzumab 440 mg:https://extranet.who.int/prequal/news/first-biosimilar-product prequalified. Based on the foregoing, the firm claimed that its eviodent that Trastuget 440 mg by Getz Pharma fails to satisfy the mandatory requirements specified in Clauses X and XI of the tender documents. Therefore, the firm requested a comprehensive re-evaluation of the technical assessment conducted for Trastuget 440 mg to ensure strict adherence to all stipulated criteria

Decision: Mr. Shabbir Khan Commercial Manager of M/S Roche Pakistan pleaded the case before the grievances committee. Mr. Imran Answer Senior Sales Manager defended the grievance on behalf of M/S Getz Pharma. The petitioner presented the above-mentioned grievance. The defendant stated that the heritage Trail is co-sponsored by M/S Biocon Biologics India & M/S Mylan India and presented a reference of FDA. The defendant further stated that the biosimilar studies are conducted to demonstrate that generic drug is bioequivalent to brand-name drug. He further stated that M/S Biocon Biologics India produces finished product Trastuzumab and offers to different

countries with different brand names and presented a Certificate of Pharmaceutical Product issued from Government of Karnataka to support its claim. In lieu of above facts the committee observed that the product manufactured by M/S Biocon Biologics is biosimilar **and upheld the decision of Technical Evaluation Committee in clause (xi) of Compulsory Parameters.** The defendant further stated that its product also qualifies the requirements of clause (xii) of Compulsory Parameters and has been qualified by the Technical Evaluation Committee. He stated that WHO has granted prequalification status to Trastuzumab 420mg & 440mg manufactured at M/S Biocon Biologics through No. BT-0N017 & BT-ON014. He further stated that Trade names are not prequalified by WHO and proprietary names given as example only. WHO prequalifies the Finished Pharmaceutical Product irrespective of trade names. The defendant further claimed that its offered product is WHO approved. **The committee decided to uphold the decision of Technical Evaluation Committee in this respect as well.**

ITEM NO. 09: **GRIEVANCE SUBMITTED BY M/S B.F. BIOSCIENCES (TENDER: M01 DRUGS/ MEDICINES 2024-25)**

GRIEVANCE DETAIL: The firm submitted the grievance that (Filgen 300mcg) Inj. Filgrastin 0.3mg has been disqualified on the grounds of "non-provision of Accredited Lab Bio Similarity studies data/report," as stipulated in Clause (xii) COMPULSORY PARAMETERS of the tender requirements. Clause xii mandates the submission of Bio Similarity Studies data, specifying that: "The bidder must submit bio similarity studies data of quoted item (for biologicals and biotech products). The biosimilar study must be from DRAP notified labs or WHO / JpMHLW / EMA / US FDA approved / accredited labs only OR quoted product must have status of reference product for biosimilar studies on US-FDA/registered at EMA official websites.". The firm claimed that this particular clause disadvantages numerous prospective bidders, including BF Biosciences Limited and could compel hospital to rely on local purchase (LP) options, resulting in significantly higher procurement costs or facing the non-

supply of essential medicines. The firm stated specific concerns as: Absence of Local Facilities to Conduct Bio Similarity Studies: Currently, there are no testing laboratories within the country—whether DRAP-notified or accredited by international agencies—have the capability to conduct biosimilar studies. Consequently, bidders would be compelled to conduct these studies abroad, incurring significant cost and time, and expending valuable foreign exchange; Impact on Hospitals' Budget and Quality Concerns: In the event that no bidder qualifies, the hospital would need to resort to local purchase at higher prices. These financial burdens could strain already limited budgets. Furthermore, biosimilar study does not necessarily correlate with better quality. For instance, Filgen has been used satisfactorily for many years by prestigious government institutions without any issues related to clinical efficacy or desired outcomes; Shortage of Imported Medicine: Over the past year, there has been a shortage of imported medicines. This scarcity has caused hospitals to incur financial losses, ultimately affecting poor patients who rely on these critical medications ; Compliance with PPRA Act 2009 particularly the clauses: Clause 10 (1) - Specifications: A procuring agency shall determine specifications in a manner to allow the widest possible competition which shall not favor any single contractor nor put others at a disadvantage. Clause 26 (2) - Reservations and Preference: A procuring agency shall allow for a preference to domestic or national contractor in accordance with the policies of the Government and the magnitude of price preference to be accorded shall be clearly mentioned in the bidding documents under the bid evaluation criteria. Clause 34 - Discriminatory and Difficult Conditions: Save as otherwise provided, no procuring agency shall introduce any condition,

which discriminates between bidders or which is difficult to meet.

In light of the foregoing, the firm requested a thorough review of COMPULSORY PARAMETERS of "Clause xii" as it pertains to "(T.E No.46)". The firm requested that this clause be reconsidered and temporarily suspended until the requisite infrastructure for conducting Bio Similarity Studies is

established within the country. Alternatively, the firm suggested to move this clause to the ordinary parameters to ensure equitable opportunities and open competition for all bidders.

Decision:

Mr. M. Saeed, Manager Institutions pleaded the case of M/S Biosciences before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid for T.E. 46 due to failure in clause (xii) of Compulsory Parameters. The firm's representative shared a link of Clinical Investigator Status while claiming that Faculty of Topical Medicine Mahidol University Bangkok Thailand is an FDA approved facility. The committee observed that the said database pertains to Inspections of clinical investigators who have conducted studies with investigational devices as part of the Food and Drug Administration's Bioresearch Monitoring Program. The list contained list of investigators rather than FDA approved facilities for Biosimilar studies. Furthermore, the Principal Investigator, Dr. Wattana Leowattana & Analytical Investigator, Dr. Tongtavuch are also not listed in the said database. **The committee decided to turn down the grievance and uphold 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

Mr. Azeem Butt
Deputy Drugs Controller
Mayo Hospital Lahore

Dr. Sana Farooq
Senior Registrar Neurology Dept.
Mayo Hospital Lahore

Dr. Umar Nazir (Away)
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AMS(P)
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5/9/24

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