

Participants:

3. Dr. Sana Farooq
Senior Registrar Neurology Department Mayo Hospital Lahore

4. Ms. Kanwal Javed

Deputy Drugs Controller Mayo Hospital Lahore

5. Mr. Muhammad Jawad Bhatti Member
Deputy Drugs Controller Mayo Hospital Lahore

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 HOORA PHARMA (R-SML SURGICAL DISPOSABLE ITEMS)

GRIEVANCE DETAIL:

The firm submitted the grievance regarding the rejection of technical bid for Medical Devices, surgical disposables items for the fiscal year 2024-25, as stated in the uploaded technical evaluation report. The firm stated that it has carefully reviewed the objections against its technical bid and like to provide necessary documentation with the hope for reconsideration:

- Regarding Product Code are not provided; hence specification cannot verify, the firm stated that As per your given format of technical bid in the biding document items code are not required, and are ready to provide items codes with its technical proposal for verifications of specifications in DRAP Certificates.
- Regarding Sole agency agreement not attached, the firm stated that M/s
 Hoora Pharma (Pvt) Ltd., is the sole authorized distributor of Ethicon Inc.
 (Johnson & Johnson), USA for which the authority letter is enclosed with
 the letter.

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the bid and will provide again.



- 3. Regarding the issue Purchase orders not in the name of bidder, the firm stated that it has attached the quoted product market experience with
- 4. Regarding the issue of non-provision of samples, the firm stated that Unfortunately it could not provided samples for evaluation and requested provide a chance for sample evaluation.

The firm further stated that it believes that the rejection of the technical bid was based on technicalities rather than the quality and reliability of quoted medical devices. The firm claimed that its products meet the highest industry standards and have consistently delivered positive outcomes in various healthcare settings. The firm requested to reconsider the decision and evaluate its technical bid in light of the documentation provided.

Decision:

Mr. Ali Arshad, Area Sales Manager of M/S Hoora Pharma pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified T.E. 81, 93, 99, 101, 103, 105, 107, 108, 110, 112, 114, 116, 117, 118, 121, 122, 126 & 127 quoted by firm due to failure in different clauses of compulsory parameters i.e. clause (e) as product codes were not provided and specifications could not be verified; failure n clause (h) as sole agency agreement was not attached; in clause (j) as quality certifications were not attached; in clause (l) as purchase orders were not in the name of bidder, and non-provision of sample of quoted items. The firm's representative presented Certificate of Registration of Medical Device. The committee observed that the clause (e) of compulsory parameters requires product registration/ enlistment certificate in the name of bidder, however, in the instant case the DRC has been issued in the name of M/S Johnson & Johnson Pakistan (Pvt) ltd. while the bidder is M/S Hoora Pharma. The firm remained non-responsive in clause (e) of compulsory parameters. The firm further stated that it does not have sole agency agreement as required under clause (h) of compulsory parameters.

The firm remained nonresponsive.

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ITEM NO. 02:

GRIEVANCE SUBMITTED BY M/S CARDIAC CARE (R-SML SURGICAL DISPOSABLE ITEMS)

GRIEVANCE DETAIL:

The firm submitted the grievance that regarding T.E# 21 Surgical Face, the Valid Drug Registration Certificate is attached on page 27, the CE Certificate is connected on pages 31-45, and the validity of the transition period is mentioned on page 32. The firm claimed that all these references are taken from the submitted technical Bid.

Regarding T.E# 38 Embolectomy Catheter 4F, the firm stated that the CE Certificate is connected on pages 36-39, and the validity of the transition period is mentioned on page 36. The Free Sale Certificate is mentioned on pages 40-60 and the experience is attached on pages 64-68 and these all references are taken from the submitted technical Bid.

Regarding T.E# 103, 105, 118, 120, the firm claimed that the Valid Drug Registration Certificate is attached on pages 27-35, the CE Certificate is connected on pages 38-48, The Free Sale Certificate is attached on pages 49-99, and the experience is mentioned on pages 102-105 and all these references are taken from the submitted technical Bid. Moreover, the reference Minutes of Grievance Meeting regarding Clarification on Re/Tender on Surgical Disposable F.Y 2024-25 T.E# 103 & 105 was technically approved by the Committee.

Regarding T.E# 121, the firm stated that the CE Certificate is connected on pages 38-48 and requested to consider its product with a pack size of 1x36 per pack.

Decision:

Mr. Ali Aslam, Sales & Marketing Executive of M/S Cardiac Care pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid due to failure in different clauses of compulsory parameters i.e. failure in clause (e) for T.E. 21, 103, 105, 118 & 120; clause (j) for all quoted items; clause (k) for T.E. 38, 103, 105, 118 & 120 clause (l) for T.E. 38, 103, 105, 118 & 120; and failure in

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samples evaluation for T.E. 103, 105, 118, 120 & 121 as products out of specifications.

Clause (e) of Compulsory parameters

The firm's representative stated that the firm, has applied Registration/Enlistment application for T.E. 21 before DRAP Islamabad for which the registration is awaited. The firm further stated that it submitted grievance on the advertised specifications and it was decided to enhance competition by extending sutures specifications from 75 – 90 cm for T.E. 103, 30 – 40mm for T.E. 105 & 13-16mm 3/8 circle RB or CN 45-75 cm for T.E. 120.. The firm further stated that T.E. 118 quoted by the firm also qualifies the requirements mentioned in the specifications column but the committee observed that the firm has quoted ½ circle instead of 3/8 required in advertised specs. Dr. Omer Nazir, Assistant Professor Plastic Surgery & Burn Unit recommended the sutures quoted by the firm. The committee decided to declare T.E. 103, 105, & 120 quoted by firm responsive in clause (e) of compulsory parameters and sample evaluation.

Clause (i) of Compulsory parameters

The firm's representative showed an expired EC Certificate No. G2 073283 0046 dated 26.05.2024 issued by TUV SUD for T.E. 21 that was not CE marked. Moreover, the quoted item was not mentioned on the certificate, the extension letter from the notified body was also not in place. Then the firm presented an Attestation of CE/ EC Certificate in favor of Vygon France issued by GMED for T.E. 38 mentioning expiry date of certificate 28.05.2024. The firm could not present any extension letter from GMED or other NANDO notified body. The firm representative stated that the firm has requested GMED for extension letter that has not been received so far. However, the firm provided a confirmation letter from QMED in favor of Peter Surgical for T.E. 103, 105, 118, 120 & 121. The committee decided to declare 103, 105, 118, 120 & 121 responsive in clause (j) of compulsory parameters.

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Clause (k) of Compulsory Parameters

The firm's representative stated that it has attached Free Sale Certificate in favor of Peter Surgical by CCI Paris ILE-DE France and the TEC has qualified T.E. 121 having Peter Surgical source while T.E. 103, 105, 118 & 120 belongs to the same principal. The committee decided to declare T.E. 103, 105 & 120 responsive in clause (k) of compulsory parameters. The firm further stated that it also has FSC for T.E. 38 and provided FSC issued by Bezirkaregierung Koln Germany. The committee decided to declare T.E. 38 responsive in clause (k) of compulsory parameters.

Clause (I) of Compulsory Parameters

The firm's representative stated that T.E. 38 has sufficient product experience to qualify the requirement of this instant clause. The firm provided Purchase Order No. PC/65503/MH dated 28.10.2021 issued by Mayo Hospital Lahore. The committee declared T.E. 38 responsive in clause (I) of compulsory parameters. The firm failed to present sufficient product experience for T.E. 103, 105, 118 & 120.

In conclusion the bid stands responsive for T.E 121 only.

ITEM NO. 03:

GRIEVANCE SUBMITTED BY M/S EASTERN MEDICAL CARE (R-SML SURGICAL DISPOSABLE ITEMS)

GRIEVANCE DETAIL:

The firm submitted the following grievances with reference to the tender of Surgical items for T.E 75 Surgical Gloves Latex Sterile (8.0) & Powered. The firm stated that its bid has been rejected Rejection due to reason that ISO 10282 is not mentioned on label of product and less than 3 Years Experience. The firm claimed that its quoted brand is world leading brand; registered from DRAP under registration no. MDIR-0004918. The firm was ready to undertake that its quoted gloves meet the international standards of ISO 10282 for which the declaration of same from the Principal firm is enclosed for record that can also be verified from Quality Assurance Certificate issued from plant (COA). The firm was also ready to undertake

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that the supply will be made with the updated label as demanded by the hospital with ISO 10282. Moreover, the firm mentioned that the same matter has been already approved in Tender 2023 – 24 (A-13). The firm also claimed that 3 Years experience is already attached with the bid however copies are enclosed again for approval.

Decision:

Mr. Abdu Salaam, Regional Sales Manager of M/S Eastern Medical Care pleaded the case before the grievances committee. The committee observed that the Technical Evaluation Committee has disqualified the bid due to failure in clauses (I) of compulsory parameters due to lack of product experience and failure in sample evaluation as ISO 10282 quality certificate was not attached. The firm's representative stated that its quoted product has sufficient product experience and was qualified in the previous tender of Mayo Hospital Lahore. He provided Purchase Order No. P.O. PKLI Hospital 01-202200524 dated 08.03.2022 issued by PKLI Lahore in favor of T.E. 75. The committee decided to declare firm responsive in clause (I) of compulsory parameters. The firm further presented a declaration letter from ASAP International SDN BHD Malaysia that the product meets the requirements of ISO 10282:2014. The firm also stated that the firm quoted the same product in previous A013 Surgical Disposable Items of Mayo Hospital Lahore which was declared responsive after reevaluation on same grounds. The committee observed that the product quoted by the firm needed to be evaluated on the basis of thickness as per ISO 10282:2014 and the disqualification of item with the comments "ISO 10282:2014 quality certificate not attached" is not tenable. Moreover, the same product has already been qualified on the same grounds in the previous tender of Mayo Hospital Lahore A013: Surgical Disposable Items and decided to declare T.E. 75 quoted by the firm responsive in sample evaluation.

ITEM NO. 04:

GRIEVANCE SUBMITTED BY M/S AKRAM BROTHERS & CO. (R-SML SURGICAL DISPOSABLE ITEMS)

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GRIEVANCE DETAIL:

The firm submitted the grievances that most items of WEGO Sutures have been rejected in Technical Meeting of Mayo Hospital, Lahore due to the following reasons:

- Regarding Less than 2% Bid Security: The firm stated that it has attached
 a bid security amount of Rs.672500 while actually it is the amount of
 Rs.677511. This minor difference is just because of a mistake during the
 making of quotation, the firm requested to compensate this mistake and
 provide the bid security to the hospital of the amount making this
 difference.
- 2. Regarding the issue of Product codes not provided in the DRAP Registration Certificates, the firm stated that In the TEC report, it is objected that for items no 106,110,114,116,120,125,126, the product codes of these items are not provided in the DRAP registration, the firm stated that all items codes are randomly provided in the registration certificate that the firm can verify.
- 3. Regarding CE Certificate not attached, the firm claimed that the Valid CE Certificates for all the items are attached in the bid & providing again.
- 4. Regarding the issue of less Experience of quoted products, the firm claimed that the experience of all the quoted items in the form of supply orders of the previous years is already attached in the bid & and providing again.
- 5. Regarding the Rejection of samples, the firm claimed that its sutures are being supplied almost in all main Government and Private Hospitals of Pakistan like Holy Family Hospital, KPK MCC for which the award letters of these hospitals are attached.

The firm further stated that it didn't get any technical complain from these institutes and have never been rejected technically. WEGO Sutures are being supplied in Pakistan at lowest rates with good quality so that maximum needy patients can be obliged. The firm requested to reassess the WEGO Sutures.

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The firm's representative was absent. The committee observed that the Technical Evaluation Committee has disqualified the bid due to failure in different clauses of compulsory parameters i.e. failure in clause (a) for all quoted items due to less bid security; clause (e) for T.E. 106, 110, 112, 114, 116, 120, 125 & 126; clause (j) for T.E. 99; clause (l) for T.E. 99, 105, 106, 107, 110, 112, 114, 118, 120, 124, 125, 126 & 127; and failure in sample evaluation due to products out of specs for T.E. 106, 110, 112114, 116, 120, 125 & 1262. The firm's representative was absent and did not come to present any document to support clause (a) of compulsory parameters. Furthermore, the firm attached an invalid EC Certificate M2020.106.13488-1 with grievance letter that has been expired on 27.05.2024. The firm attached a Notified Body Confirmation Letter issued by UDEM Adriatic d.o.o Croatia dated 05.03.2024 that clearly states that Notified body has not taken responsibility for appropriate surveillance of corresponding devices i.e. Synthetic Absorbable Sutures under MDD The firm also did not attach any documents to challenge the decision of TEC in clause (I) of compulsory parameters. The firm representative was not present to challenge the decisions of TEC in the sample evaluation. The committee decided to uphold the decision of Technical Evaluation Committee.

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

Mr. Mulammad Jawad Bhatti

Deputy Drugs Controller Mayo Hospital Lahore MS. Kanwal Javed

Deputy Drugs Controller Mayo Hospital Lahore

Dr. Sana Farooq

Senior Registrar Neurology Dept.

Mayo Hospital Lahore

Dr. Umar Nazir

Assistant Professor Plastic Surgery

Mayo Hospital Lahore

Dr. Nasir Chaudhary

HoD Obhthalmology Department

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As per tules,