APPEAL No. KPPRA/GRR/Appeal/94 of 2021

M/S Hashir Surgical Services through CEO Asghar Ali Shah, House No. 16, Street No. 1, Sector F-2, Phase-6, Hayatabad, Peshawar. ----------**Appellant**

Versus

1. Director General, Health Services, Chairman, S&RCC Govt. MCC, Khyber Pakhtunkhwa, Peshawar.
2. Director, Government Medicine Coordination Cell (MCC), Peshawar.
3. Chairperson, T&E Committee MCC, Peshawar.
4. Director General, Drug Control and Pharmacy Services, Khyber Pakhtunkhwa, Peshawar.
5. Secretary, Health Department, Government of Khyber Pakhtunkhwa, Peshawar.

---------- **Respondents**

Appeal Proceedings:

This appeal has been filed under Section 35(1)(b) of the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012 read with Rule 7(1)(c) of the Khyber Pakhtunkhwa Public Procurement Grievance Redressal Rules, 2017 by M/S Hashir Surgical Services through CEO Asghar Ali Shah, House No. 16, Street No. 1, Sector F-2, Phase-6, Hayatabad, Peshawar (hereinafter "the Appellant") against the followings:

1. Director General, Health Services, Chairman, S&RCC Govt. MCC, Khyber Pakhtunkhwa, Peshawar.
2. Director, Government Medicine Coordination Cell (MCC), Peshawar.
3. Chairperson, T&E Committee MCC, Peshawar.
4. Director General, Drug Control and Pharmacy Services, Khyber Pakhtunkhwa, Peshawar.
5. Secretary, Health Department, Government of Khyber Pakhtunkhwa, Peshawar.

(hereinafter "the Respondents").

Upon receipt of the subject appeal under Section 35 of the KPPRA Act, 2012, the same was admitted for regular hearing, where after the Managing Director, KPPRA nominated Mr. Muhammad Fakher-e-Alam Khan, Chief Coordinator, Commissionerate Afghan Refugees, Khyber Pakhtunkhwa, and Mr. Muhammad Sheraz, Director Finance, Mardan Medical Complex, as a panel of Technical Assistants from the approved list of Technical Assistants under Rule 10 (2) of the Khyber Pakhtunkhwa Public Procurement Grievance Redressal Rules, 2017 and entrusted them to submit the recommendations vide No. KPPRA/GRR/Appeal/94 of 2021/911 dated 15.10.2021 **(F/A)**. A copy of the appeal along with supportive documents were provided to the panel **(Flag B; Pages 1-18).**

Proceedings and Evidence:

2. The nominated panel of Technical Assistants examined the appeal and attached documents on 15.10.2021. Summons were issued to the parties to appear along with record and relevant documents before the panel in the office of KPPRA on 21.10.2021**(Flag C and D)**.
3. The following points were selected for consideration and proceedings in the appeal:
   a) Has the procuring entity/end users/MCC experts/consultants rightly applied the evaluation criteria and correctly recommended the appellant to be declared as non-responsive for the quoted item No. 985 i.e. 0.5 Auto Disable Syringe for Immunization Brand name Revitale CDY?

   b) Has the Procuring Entity treated the grievance application/complaint in the prescribed manner, and the impact of non-conformity, if any, on the procurement process?

4. The hearing of the case was held by the nominated panel of Technical Assistants in the office of KPPRA on 21.10.2021. Mr. Mohammad Taif Khan, advocate, Mr. Arsalan Sareer, advocate, Naseeb Gul and Asghar Ali Shah represented the Appellant while Dr. Inam Ul Haq, Deputy Director, Miss Ume Kalsoom and Hidayat Ullah, MCC, DG Health, KP represented the Respondents. The attendance sheet is attached as **(Flag E**).
5. The learned counsel for the Appellant stated the brief facts of the case by referring to the memorandum of appeal and the documents annexed thereto, and elaborated that:
   a) The appellant is a registered firm and deals in medical devices with the name and style "Hashir Surgical Services" the appellant is doing business with the Health Department and participating in the process of procurement of medicine.
   b) Directorate of Health Services (DGHS), Khyber Pakhtunkhwa published an invitation for bids through "Government Medicine Coordination Cell (MCC)", Directorate General Health Services Khyber Pakhtunkhwa for selection and rate contracting of drug/Medicine, Medical devices Surgical Disposable and non-drug items for the year 2021-22.
   c) The appellant submitted bids for various items, wherein item No. 985 i.e. Auto Disable Syringe for Immunization with Brand Name Revitale CDY was not recommended on the following grounds;
      1. *Revitale healthcare Kenya Item No. 985 is not recommended by End User/MCC expert/Consultant.*
   d) Non-recommendation of the appellant on the basis of physical examination by the end user/doctor is illegal as the said quoted item has been tested by the DTL and such specification has also been approved by the World Health Organization (WHO).
   e) That according to the law mere examination held by persons/individuals, the standard and specification of such item cannot be questioned. A group of individuals who are

otherwise not the sector/item experts cannot ascertain the quality parameters and decide the sterility and pyrogen free tests with other specifications. Similarly, the fact that such quoted item is used for the immunization of vaccine was also ignored, for which the standard of gauge required is 23-gauge needle.

f) The end user/doctor also ignored the fact that effectiveness of the quoted item will be reduced if gauge of needle was put below 23-gauge as the vaccine is dense in the nature and it cannot be easily injected if the gauge of the needle is below 23-gauge.

g) The appellant filed a complaint u/s 35(1)(a) of the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012 to the Secretary Health/Respondent No.5 on 20.09.2021, vide diary No. 17710, which was pending disposal within stipulated time period, hence the instant appeal has been filed.

h) The appellant most humbly requested that on acceptance of this appeal, the respondent may please be directed to revise the approved bid evaluation report of MCC bid 2021-22 and the appellant may be declared as qualified being responsive in all required specification and documentation to save the money of public exchequer. It was further requested that till the final decision in the instant appeal, the DG Health/Respondent No.1 may please be restrained to award the contract for the above mentioned items.

6. The learned counsel for the respondents briefly responded on the points raised by the appellant and requested that they may be granted time to submit their written reply/statement. The panel of Technical Assistants allowed the request of the respondents and allowed to submit written response to the office of Registrar of Appeals, KPPRA on 27.10.2021 along with the supporting documents. The respondent again requested ROA, KPPRA that the submission date of written reply may kindly be extended upto 02.11.2021, which was granted by the panel of TA's. On 02.11.2021 vide letter No. 5717/DG, DC&PS/MCC/KP the respondent submitted written statement and supporting documents **(Flag G; Annexes I-IX)**. Copy of the same has been shared with the appellant through the office of ROA, KPPRA**.** The respondents stated the following points;

   a) The appellant has concealed the whole truth and material facts. The appellant has not come with clean hands. The appellant has mala fide intentions. The appellant is estopped by his own conduct and his appeal is liable for dismissal.

   b) The respondents have described the general procedure for framework agreement of Government Medicine Coordination Cell (MCC) for procurement of medicines, involving advertisement in the press, submission of bids, opening of technical bids, evaluation of product wise evaluation of the firms, technical and performance evaluation of the disposable items by a panel of experts, and testing of items by the Drug Testing Laboratory (DTL). According to respondents the process of evaluation of bidders have been undertaken by the Technical and Evaluation (T & E) Committee, which assist the Selection and Rate Contracting Committee (S & RCC) being the final authority for approval of the cases. The evaluation is

followed by physical inspections of the firms to authenticate the current Good Manufacturing Practices (cGMP) and other documents. During the process any grievance or appeal is considered on its merit. The same procedure was applied in the instant procurement.

c) The appellant deals in the items which fall under the category of medical devices, surgical disposables and non-drug items, including the following items;

   1. *Formulary No. 985 (auto-disable syringe 0.5 ml) manufactured by M/S Revitale Healthcare Kenya.*

d) The respondent further submitted that the items quoted by the appellant were not technically qualified due to non-fulfillment of the technical evaluation criteria/parameters set forth in the advertised standard bidding documents (SBDs) for the year 2021-22 covered in section II (ITB 25.4), SCC Section 5(iv) & (viii), section V (F) (v) and technical evaluation proforma for the import of medical devices at column No. 18 & 19 of the advertised SBDs Govt. MMC FY 2021-22 **(Flag G; Annex-I).**

e) The appellant firm participated in open bidding competition and has successfully been selected for thirty-three (33) items on the basis of best evaluated bids in Govt. Medicine Coordination Cell, KP for the year, 2021-22, copy of the contract agreement is at **(Flag G; Annex-IX)**.

f) The appellant has filed the instant appeal for its quoted formulary item No. 985, which is not recommended during the course of technical evaluation due to non-adherence to quality and prescribed standards as defined in the SBDs.

g) Detail of the item in question is reproduced as under along with facts and decisions of the procurement committee as per advertised criteria;

   i. M/S Revitale Healthcare Kenya, Item Formulary No. 985 (auto-disable syringe 0.5 ml) is not recommended by End Users/MCC Experts/consultants.

h) The respondent in their written statement produced the decision of the S&RCC/Procurement Committee and stated that the samples provided by the appellant to the MCC panel of experts/End Users/Consultants (Surgeons, Nephrologists, Physicians, Senior Nurse/Dialysis Technician) notified vide Annex-VI for physical examination/evaluation of the items as a mandatory requirement for the technical evaluation process mentioned in the SBDs at Section II(ITB 25.4), SCC Section 5(iv) & (viii), section V (F) (v) and technical evaluation proforma for the import of medical devices at Column No. 18 of the advertised SBDs Govt. MMC FY 2021-22 **(Flag G; Annex-VIII) .**

i) It is further stated in the written reply of the respondent that 05 members of the panel of experts/End Users/Consultants have not recommended the quoted item at formulary No. 985 of the appellant due to the adverse observation, which is reproduced in the End Users/Consultants report (**Flag G; Annex-VII).**

j) The respondent further stated that the items quoted by the appellant falls under the Category of therapeutic goods, which are used for parenteral medicaments in critical conditions at hospitals. Non-fulfillment of the end user satisfaction of such items shall lead to life threatening and serious consequences.

k) In addition, the mandatory technical evaluation of the quoted medical devices/surgical disposables etc. at DTL for test analysis according to official monographs and pharmacopoeias/standard/analysis parameter and physical examination/evaluation by the MCC panel of experts/End users/Consultants of all bidders, as system breaking points, are binding requirements mentioned in the SBDs at Section II(ITB 25.4), SCC Section 5(iv) & (viii), section V (F) (v) and technical evaluation proforma for the import of medical devices at Column No. 18 & 19 of the advertised SBDs of Govt. MMC FY 2021-22. **(Flag G; Annex-I & II).**

l) The respondent stated that the appellant statement regarding physical examination of the quoted medical devices etc. by MCC panel of expert/End user/consultant is incorrect and misleading. The procuring entity during procurement process conducted evaluation through highly qualified technical experts/consultants in a transparent and professional manner. Notification of MCC panel of expert/End users/consultants is produced which is attached as (**Flag G; Annex VI).**

m) It has been again stated by the respondent that (05) five members of the MCC panel of expert/End users/consultants have not recommended the quoted item at formulary No. 985 of the appellant due to adverse observations, which are reproduced as such "painful phlebotomy, phlebitis risk and contraindicated in neonates" hence not due to gauge requirements.

n) The sterility and pyrogen test of the quoted items are conducted at DTL along with all relevant test analysis which are required according to the official monographs, pharmacopoeias/standard ISOs and analysis parameters. The same item was physically failed to satisfy MCC panel of experts due to risk of phlebitis and contraindication in the neonates during immunization.

o) The Respondent prayed that the instant appeal has no material, a plethora of distorted facts, which has got nothing with the procurement process. The same is merely due to the ignorance of procurement laws and policy of the procuring entity which has taken its effect while finalizing rate contracting. The instant appeal on the bases of incorrect, distortion of facts and ulterior motives shall directly affect the patients in free provision of lifesaving medicines being exclusively used in immunization and intravenous catheterization in critical conditions at hospital settings. The Govt. MCC Khyber Pakhtunkhwa is a notified body with defined TORs. The selection of items are based on the qualification of all the technical criteria/parameters for the respective firm/items. In the case of appellant, the

products were examined by MCC panel of experts for purpose of safety, efficacy, potency, quality and cost effective selection of the items. All parameters were critically checked and documented as per advertised criteria. However, the quoted item at formulary No. 985 did not qualify due to non-fulfillment of the requisite technical evaluation criteria/parameters in the advertised bidding competition. Therefore, it is requested that the instant appeal may be dismissed for the supply and availability of the lifesaving medical devices to the poor, deserving and critically ill patients.

Discussion and Findings:

8. The proceedings in the case revealed the following position about the points for determination and points at variance:
   a. Whether the procuring entity/end users/MCC experts/consultants rightly applied the evaluation criteria and the PE has correctly not recommended the appellant's quoted item No. 985 i.e. 0.5 Auto Disable Syringe for Immunization Brand name Revitale CDY. The relevant criteria for evaluation of technical bid given in the SBDs are reproduced below;

Section V. Technical Specifications

Technical Evaluation Criteria for Drugs / Medicines, Medical Devices, Surgical Disposables and Non-Drug Items (NDIs)

F. Importers of Medical Devices (excluding Cardiac Stents)

v. Samples of devices will be tested and evaluated by the Drugs Testing Laboratory as well as by panel of experts/end users and the quoted item/s may be disqualified for further competition on the report/s of these entities.

Special Conditions of Contract

5. Inspection and Tests (GCC Clause 8 and in accordance with the clauses of contract with the Procuring Agency)

iv. Medical Devices, Surgical Disposables and NDIs shall be examined and/or tested by MCC experts/s of the T&E Committee, and/or of the S&RCC of the Government MCC in a manner as deemed relevant and appropriate (including testing at Drug Testing Lab or elsewhere) for the purpose by the said expert/s, and as laid down, or otherwise, in the applicable laws and Rules, for submission of technical report to the relevant forum/quarter for the needful.

viii. The application fee charges of @ Rs. 5000/bid seems rational to carry out the purpose of soliciting the bidding documents as the same is considered as fee not only considering the cost of the documents but to achieve multiple steps relating to the procurement process including the product wise evaluation of the firms, technical & amp; performance

evaluation of the disposable items at their premises across the country by the panels of Pharmacists, consultants (physicians, surgeons, etc.) and other experts/end users and quality assurance parameters / specifications through chemical analysis in adherence to the standard specification of the offer bid as per provision of The Drug Act and rules frame their under.

Technical evaluation proforma for the import of medical devices column No.18 & 19 of advertised SBDs Govt. MCC FY 2021

Evaluation Criteria for Importers of Medical Devices, Govt. MCC 2021-22	
Product Technical Evaluation	
Column 18	*Column 19*
Samples evaluation by DTL(Failure to comply with the relevant standards shall lead to Disqualification of the quoted product)	*Physical examination of the quoted item/s by the MCC expert/s shall lead to disqualification of the said item*

The above conditions stipulate that samples of devices will be tested and evaluated by the Drugs Testing Laboratory (DTL) and panel of experts/end users and the quoted item/s may be disqualified for further competition on the report/s of these entities. Moreover, according to Evaluation Criteria provided in technical evaluation proforma for Importers of Medical Devices, product technical evaluation in column 18 it has been stated that Samples evaluation by DTL(Failure to comply with the relevant standards shall lead to Disqualification of the quoted product) and column 19 states that Physical examination of the quoted item/s by the MCC expert/s shall lead to disqualification of the said item. Based on evaluation criteria provided in the bidding documents and record provided by the respondent was perused to find out the DTL report for the item No. 985 in said case. From the perusal of record submitted by respondent it was revealed that the DG Health Services KP/Chairman S&RC Committee Govt. MCC 2021-22 has sent a letter No. 2126-28/MCC/KP, dated 17.06.2021 to the Director/In-charge, Drug Testing Laboratory, Khyber Pakhtunkhwa and enclosed the samples of the medical devices, surgical disposables and cotton related items in the Govt. MCC tender 2021-22 for the test/analysis along with list (01 page) of firms and cartons vide letter No. 2126/MCC/KP dated 17.06.2021 **(Flag G; Annex V)**. however, there is no reply available on record from the Director/In-charge, Drug Testing Laboratory (DTL), Khyber Pakhtunkhwa, which was the evaluation criteria in SBDs for compliance with standards; and in case of failure to comply with the relevant standards shall lead

to disqualification of the quoted product. Nor the respondent has contested that the DTL report of the appellant has failed, so the same criteria in the instant case in hand has not been the reason for disqualification of the appellant firm. The other evaluation criteria/parameter provided in the SBDs was the physical examination of the quoted item/s by the MCC panel of expert/end users. The documents provided by the respondent were perused wherein it was noticed that the DG, Health Services, KP Chairman S&RC Committee has sent a letter to Heads of the MTIs, IKD, Services Hospital and DHQ hospital regarding the MCC expert/end user/consultants committee for the selection & Rate contracting of Medicines/Drugs, Medical Devices, Surgical Disposables & Non-Drug items for the FY 2021-2022 Govt. MCC, KP **(Flag G; Annex-VI)**. List of the samples for DTL/End users for the year 2021-22 of Hashir Surgical Services is available on record (06 pages); at serial No. 5 under the column "Trade name" Revitale CADY, column "Specification" 0.5 ML, under the last column "DTL/End user report" painful phlebotomy and contraindicated in neonates remarks has been reflected. Apart from said comment, there is nothing available on record or any report that could have been relied upon for rejection of item No. 985 i.e. 0.5 Auto Disable Syringe for Immunization Brand Name Revitale CDY.

The complaint dated 14.09.2021 filed by the appellant is still pending with the Respondents. In terms of Rule 6 of the Khyber Pakhtunkhwa Public Procurement Grievance Redressal Rules, 2017, the Grievance Redressal Officer/Committee was duty bound to decide the complaint within 5 days and convey the decision to the complainant/appellant within 3 days.

Recommendations of the Panel of Technical Assistants:

In view of the foregoing discussion and conclusions, and in terms of Rule 10(8) of GRR read with item 22 of Guidelines GR, the panel of Technical Assistants recommends that the evaluation criteria provided in the Standard Bidding Documents has not been applied objectively and the detailed expert report is missing. Keeping in view the health implication of the subject, it is recommended that the detailed expert inspection report (expressing an objective, evidence-based and data-based feedback on the basis of which the product was rejected) may be submitted to Authority for the final decision.

Decision of the Authority:

Memo of appeal along with available record, proceedings conducted by the panel of Technical Assistants (TAs) so nominated in the instant appeal, statements/documents submitted by the parties thereto and recommendations of the panel of Technical Assistants have been perused and examined thread bare.

In light of the above, the Authority under the provision of Section 35 of the KPPRA Act, 2012 and the Powers conferred upon by the Board of Directors (BoD) of the Authority, while agreeing with the recommendations of panel of Technical Assistants has reached to the conclusion that the appellant submitted bids for various items, wherein the item No. 985 i.e. Auto Disable Syringe for Immunization Brand Name Revitale CDY was not recommended by End Users/MCC experts/Consultants. However, there is no reply available on record from the Director/In-charge, Drug Testing Laboratory (DTL), Khyber Pakhtunkhwa, which could be relied upon to decide about qualification/disqualification of the said item. Similarly, the other evaluation criteria/parameter provided in the BSDs is the physical examination of the quoted item/s by the MCC panel of experts/end users. As per available record, DG, Health Services, KP Chairman S&RC Committee sent a letter to Heads of the MTIs, IKD, Services Hospital and DHQ hospital regarding the MCC experts/end users/consultants committee for the selection & Rate contracting of Medicines/Drugs, Medical Devices, Surgical Disposables & Non-Drug items for the FY 2021-22 of Govt. MCC, KP. List of the samples for DTL/End users for the FY 2021-22 of Hashir Surgical Services is available on record (06 pages); at serial No. 5 under the column "Trade name" Revitale CADY, column "Specification" 0.5 ML, under the last column "DTL/End user report" with following remarks "painful phlebotomy and contraindicated in neonates". Apart from the said comment, there is nothing available on the record or any report that provides the basis for rejection of item No. 985 i.e. 0.5 Auto Disable Syringe for Immunization Brand Name Revitale CDY.

Since the evaluation criteria provided in the BSDs has not been applied objectively and the reports of both DTL and MCC panel of experts/end users/Consultants are missing. Therefore, the Respondent(s) are directed to re-evaluate the item No. 985 i.e. Auto Disable Syringe for Immunization Brand Name Revitale CDY in the light of DTL report within 05 days and proceed on merit in accordance with the law and BSDs.

-Sd-
Managing Director
KP Public Procurement Regulatory Authority

Registrar of Appeals, KPPRA

Dated: 14/12/2021

Registrar of Appeals
Government of Khyber Pakhtunkhwa,
Public Procurement Regulatory Authority