GOVERNMENT OF SINDH
SINDH PUBLIC PROCUREMENT REGULATORY AUTHORITY

NO.AD (L-II)/SPPRA/CMS-2074/2020-21/4009 Karachi, dated the 16th March, 2021

To,

Section Officer (PM & I Cell),
Health Department,
Government of Sindh,
KARACHI.

Subject: **DECISION OF REVIEW COMMITTEE OF SINDH PUBLIC PROCUREMENT REGULATORY AUTHORITY.**

The undersigned is directed to refer to the subject cited above and to enclose herewith a copy of the Authority's Review Committee decision (**M/s Global Marketing Services V/s Section Officer PM & I Cell Health Department,** held on **27.01.2021 & 10.02.2021**for taking further necessary action in compliance of referred decision, under intimation to this Authority, at the earliest.

ASSISTANT DIRECTOR (LEGAL-II)

A copy is forwarded for information and necessary action to:

1. The P.S to Secretary to Government of Sindh, Health Department.
2. The Additional Secretary (PM & I CELL), Health Department Karachi.
3. Assistant director (I.T), SPPRA **(with advice to post the decision on the Authority's website in terms of Rule-32(11) of SPP Rules, 2010)**
4. The Staff Officer to the Chairman / Members Review Committee.
5. The Appellants.

GOVERNMENT OF SINDH
SINDH PUBLIC PROCUREMENT REGULATORY AUTHORITY

NO.AD (L-II)/SPPRA/CMS-2074/2020-21/ Karachi, dated the March, 2021

BEFORE REVIEW COMMITTEE OF SINDH PUBLIC PROCUREMENT REGULATORY AUTHORITY UNDER RULE-32 OF SPP RULES 2010.

(Appeal)

M/s Global Marketing Services(appellant)

Versus

The Section Officer PMI cell Health Department, Government of Sindh (Procuring Agency)

(**NIT T00911-20-0003** dated 02.11.2020)

Facts and background

1. The appellant[1]**M/s Global Marketing Services,** lodged a complaint **(vide letter dated 01.12.2020)** addressed to the Secretary Health Department, Chairman Complaint Redressal Committee, against the **NIT T00911-20-0003** dated **02.11.2020** that was floated by the Section Officer PMI cell Health Department "procuring agency". (under Central Procurement Committee). The appellant complained that the procuring agency has disqualified the appellant due to **sensitivity and interpretation issues in the Covid PCR kits**. Therein the procuring agency called the of CRC wherein the complaint of the appellant was not accepted CRC and same was rejected.

2. Subsequently, the appellant (vide letter dated **24.12.2020**) preferred an appeal before the Review Committee of SPPRA and submitted review appeal fees[2] .He stated that CRC rejected the complaint. The Authority listed the matter in a meeting of the Review[3] committee of SPPRA that was scheduled to be held on **Wednesday, 27thJanuary 2021 at 11.00 a.m.& 10th February 2021** under the Chairmanship of Managing Director, SPPRA in Committee Room of Sindh Public Procurement Regulatory Authority, Barrack No.8, Sindh Secretariat Block-4-A, Court Road, Karachi, **for hearing of the appeal of the appellant** in terms of Rule-31(5) read with 32[4] SPP Rules, 2010(amended up-to-date).

M/s Global Marketing Services,111 hali Road,westridge1,Rawalpindi cant, Pakistan.

[2]This Authority's Office Order No. Dir(A&FVSPPRNI8-1910325 dated 26.07.2019 [https://fipms.pprasindh.gov.pk/PPMS/]

[3]The bidder shall submit (following documents] to the Review Committee:- (a) a letter stating Ns wish to appeal to the Review Committee and the nature of the complaint; (b) a copy of the complaint earlier submitted to the complaint redressal committee

[4]Rule-32(1) provides that foe a bidder not satisfied with decision o f foe procuring agency's complaints redressal committee may lodge an appeal to foe Review Committee within ten (10) days o f announcement of foe decision provided that he has not Withdrawn the bid security, if any, deposited by him.

3. Accordingly, the appellant's case was taken up by the Review Committee[5] for hearing in its meeting re-scheduled on **27.01.2021 & 10.2.2021 at 11.00 a.m. and notices**, in this regard, were already issued to the parties concerned as mentioned above. The meeting was attended by the Chairman and the members of the Review Committee Muhammad Yameen Abbasi along-with Dr. Ghulam Fatima Chief Pathologist, Section Officer PMI health Department attended the meeting being the representative of procuring agency (Central Procurement Committee of Health Department). The meeting was also attended by **Muhmmad Ali Manager, M/s Global Marketing Services.**

REVIEW COMM ITTEE PROCEEDINGS

4. The Chairperson of the Review Committee commenced the meetings by welcoming all the participants of the meeting. Then, the chair asked the appellant to present the case/ version, on the instant procurement before the committee.

Appellant's Version *

5. The appellant submitted that NIT was floated by the Health Department wherein proposals were sought by the Department for various items including the item namely "Selection & Rae contracting of ovid-19 Amplification / Extraction Kits / Antigen Kits & VTM / Swab the Year 2020-21". The appellant submitted that his firm M/s Global Marketing Services participated in that tender & quoted SARS-OV-2 GEN® (Biomerieux, France) & Automated DNA and RNA Extraction Kits (Tianlong, china) for OVID-19 Amplification and Extraction kits respectively.

6. The firm contended that Both the quoted products were rejected by the authorities with the remarks, **"Due to technical issues of sensitivity and interpretation"**. The Firm informed that a letter was written to record our grievances against the decision & presented technical summary of quoted products for consideration:

i. COVID-19 Ampilfication kit with all consumables

Withdrawn the bid security, if any, deposited by him.

[5]On receipt of appeal, along with all requisite Information and documents, the Chairperson shall convene a meeting of the Review Committee within seven working days. It shall be mandatory for the appellant and the head of procuring agency or his nominee not below the rank of BS-19 to appear before the Review Committee as and when called and produce documents, If required. The Review Committee shall hear the parties and announces Its decision within ten working days of submission of appeal. However, In case of delay, reasons thereof shall be recorded In wilting.

SARS-OV -2 R- GENE®, manufactured by BioMerirux (France) is a real time detection kit for OVID-19. The kit is all in one reagent kit with two triplex PR to detect **3 genes (N, RdRp, & E gene).**

ii. **Regulatory Status/ certifications:**

ARGEN® kits are **IVD CE marked** according to the European Directive 98/79/E on in vitro diagnostic medial devise.

The kits are also approved under **EUA from US FDA.**

The kits are developed and are manufactured under the following certification

ISO 13485:2016

ISO 9001:2015

iii. Analytical Sensitivity:

The sensitivity of the kit is claimed as 0.43 TcID50/mL 380 copies/mL 2.58 log10 copies/mL (same claimed LOD for N, Rd Rp and E gene) for all specimen types claimed. Based on Ct values and detection rates at lower concentration, sensitivity was shown to be slightly better for the N gene compared to the E gene and the Rd Rp gene.

iv. Clinical Performance Evaluation:

The clinical evaluation of the SAR□COV□2 □R – GENE® kit was conducted with clinical nasopharyngeal swabs in universal transport medium. Swabs were contrived with SARS□COV□2 viral strain of SARS□COV□ RNA transport to generate Positive Present Agreement (PPA), Negative present Agreement (NPA) & Overall Present Agreement (OPA).

	% Agreement for all samples		
	PPA	NPA	OPA
SAR-COV-2 detection (PCR1 and PCR2)	100%	100%	100%
SAR-COV detection (PCR2)	97.4%	100%	98.7%

In addition, the performance was validated by the French National Reference enter (Lyon, France), demonstrating 100% overall agreement for SAR—COV—2 detection (both PCR1 and PCR2).

v. **Result Interpretation:**

SARS□COV□2 R□GENE® uniquely designed format allows for specific & generic detection with PR1 (SARS-COV-2 specific) as frontline PCR and PCR2

(Sarbecovirus generic) as second line optional PCR for confirmatory test. Internal control assesses the quality of the PCR process from extraction to detection.

vi. **Ends User References:**

The kit has been widely used in international as well as local market. We are enclosing the satisfaction report for few of the well reputed labs & hospitals for your review such as;

- NIH, Islamabad
- Shaukat Khanum Memorial Hospital, Lahore
- Armed Forces Institute of Pathology, Rawalpindi / All CMHs
- NDMA, Islamabad
- Chugtai Lab, Lahore

vii. Validation by laboratory independent of the manufacturer:

ARGENE®CE-IVD kits have been validated by the independent laboratories. SARS-COV-2 R-GENE—has been validated by:

- **Viii. FIND (Foundation for innovative New Diagnostic; is a WHO collaborating Centre for Laboratory strengthening and diagnostic Technical Evolution) and**
- **The French National reference center**

Evolution results have been published on internet are enclosed for your reference.

7. **The firm further contended regarding COVID-19 Extraction Kit with all consumables and submitted that** Viral DNA and RNA extraction kits, manufactured by Tianlong (China), are fully automated extraction kits to be run on GeneRotx96, a fully automated Rotary Nucleic Acid Extraction with capacity to run 1 to 96 samples at the same time. We have offered to place the Nucleic Acid Extractor on Reagent Rental Basis

8. The firm also submitted that the products have a clear and approved Regulatory Status Certification and submitted that the same are **IVD CE marked** according to the European Directive 98/97/EC on in vitro diagnostic medical devices and The Extractor & kits are also approved by **US FDA. Besides these are** Registered by CFDA / National Medical Products Administration (NMPA)

9. The appellant also submitted that the kits are developed and are manufactured under the following certification
   - ISO 13485:2016
   - ISO 9001:2015

10.

11. The firm also claimed that there are successful End User References available for the product. Tianlong is serving more than 2,000 customers in more than 40 countries

and regions including, Korea, the United States, France, Germany, Denmark, the United Arab Emirates, Pakistan, and so on.The kit has been widely used in international as well as local market. We are enclosing the satisfaction report for few of the well reputed labs & hospitals for your review such as;

- NIH, Islamabad
- Chugtai's Lab, Lahore

12. The appellant claimed that the product has best Technical Specifications which include
    i. Rotary Mixing Technology for reduced risk of ross contamination
    ii. Fully Automated, extraction process is completed in less than 25 minutes
    iii. High Extraction Efficiency with more than 95% Recovery rate
    iv. Dedicated reagents

13. The appellant also pleaded to look at that matter and consider GMS for healthy prepetition. Satisfaction Reports, Quality certificates, and External Validation Reports are were shared for reference.

14. The appellant also informed that a letter No. **So (PM&I) 2-1/2020-21/CPC (Main)** Dated:**24th December 2020** was received for CRC decision which was held on 23-12-2020 and submitted that In that CRC meeting the complainant's grievance were not resolved and the complainant was not satisfied with CRC decision, because the decision taken was one sided.

15. The firm submitted that Both of quoted **products are CE-IVD & US FDA** approved & have been validated internationally by recognized laboratories& public health departments. Also, these kits are being used by reference laboratories such as NDMA, AFIP, CMHs & many leading private laborites. The users are highly satisfied with the results & the satisfaction reports have been submitted to the procurement authority. The complainant requested to take grievances into consideration and requested to re-evaluate o case with a more neutral perspective.

Procuring Agency's Version

The procuring agency submitted that the tenders were called on Single Stage Single Envelope Procedure by the Central Procurement Committee of Health Department.

16. The procuring agency submitted that **PROCUREMENT MONITORING & INSPECTION CELL SINDH** proposed requirement for the year 2020-21 and the same items were called by the Central Procurement Committee of Health Department

Sr.No	Name of items	
1.	COVID-19 Amplification Kits with all consumables.	
2.	COVID-19 Amplification + Extraction Kits combined with all controls / calibrators / consumables to run an Automated Analyzer.	
3.	COVID-19 Extraction Kits with all Consumables.	
4.	COVID-19 Rapid Antigen Kits (WHO approved)	
5.	VTM / SWAB (Nasopharyngeal swab)	

17. The procuring agency furthermore submitted that a meeting of CPC of Health Department was held on November 17 2020 at 11.00 A.M in the office of Vice Chancellor university of Health Sciences Karachi for the Technical opening of bids.
18. The procuring agency also submitted that Technical bids were opened and announced in detail. All members of CPC signed the bids and Financial bids were sealed in a box duly signed by the procurement Committee.

19. The procuring agency further submitted that CPC also suggested/proposed to constitute a sub-committee comprising the Technical Experts for technical Evaluation of bids and samples. The following committee was recommended by the Central Procurement Committee and the following members committee was formed by the CPC to test, analyze and evaluate the samples of COVID-19 Amplification + Extraction Kits combined with all controls / calibrators / consumables to run an Automated Analyzer/VTM/Swab.

i. Professor Dr. Ghulam Fatima,
Chief Consultant/Pathologist. Central Lab, Dr Ruth K.M Pfau Civil Hospital, Karachi

ii. Professor Dr.Saeed Khan
Head of Molecular Pathology,Dow university of Health Sciences, Karachi

iii. Assistant Professor Dr Amatul Qudoos Latif
Main Laboratory JPMC Karachi.

20. The procuring agency further submits that on the report of the sub-committee comprising the Technical Experts for technical Evaluation of bids and samples, the

bid was rejected. It was informed that the Technical committee examined all the samples submitted by all the bidders including complainant. The Technical Committee was not satisfied the samples of (Amplification/Extraction Kits) provided by the complainant.

21. The procuring agency further submitted that the bidder had approached to the CRC for redressal of grievances and CRC rejected the complaint. The operative part of the decision of CRC is reproduced as under

The CRC examined the details submitted by the complainant and discussed to issue with Chairman of Technical evaluation committee i.e. Dr. Ghulam Fatima, Chief Pathologist, and civil Hospital Karachi. She informed that the Technical committee examined all the samples submitted by all the bidders including complainant. The Technical Committee was not satisfied the samples of (Amplification/Extraction Kits) provided by the complainant.

The CRC unanimously agreed that in the light of observation of technical committee complaint of company is not valid and maintainable on technical grounds, hence, rejected.

22. Syed Adil Gilani asked the procuring agency how the samples submitted by the bidders were examined and evaluated. The procuring agency submitted that the results of samples were compared with Standard results of Abbot which are internationally recognized and validated. The procuring agency clarified that the results of the appellant were not matching with the results of **ABBOT CHECK** wherein some **Positive results** were being shown as **Negative** in the samples of the appellant.

23. The procuring agency was asked that the appellant is supplying the same kits to the different institution in the country and there found no any issue why the issue has been observed by the procuring agency? The procuring agency submitted that different institutions have different evaluation, testing and examination criteria whereas the procuring agency accepts any proposal with proper check, appropriate testing, comprehensive analysis and cross checking with Standard. In the case of the appellant the sample submitted by the appellant was found not satisfying.

24. The chairperson asked the procuring agency what is the status of the procurement in question? The procuring agency submitted that Contract has been signed with the successful bidder after the decision of CRC in accordance with the rules.

25. The procuring agency submitted that the contract has been signed at the rate of **RS.833**.

Findings of Review Committee

26. From perusal of record, statement of bidder and the procuring agency, the committee finds that the controversy involved is regarding the Technical Disqualification of the bidder by the procuring agency. The bidder has been Technical disqualified due to the issue of sensitivity and interpretation issues in the samples of kits submitted by the bidder. The bidder relies on the certification of the kits, approval of the same by international organizations and claims that these kits are being successfully used internationally as well as nationally.
27. The basic question involved is whether procuring agency should rely and evaluate on the certification of product, approval of the product and successful experience of the importer? or the procuring agency should test, analyze and evaluate itself through the samples which are taken from the bidder?

VIEW OFTHE REVIEW COMITEE

28. The committee is of the view that the procuring agency is fully authorized and free to make the decisions in accordance with the criteria mentioned in the bidding documents. The bidder is also required to accept the terms and conditions of the procuring agency which are mentioned in the bidding documents. The bidder cannot seek relief outside the terms and conditions of the bidding documents and NIT. In this matter, the committee observes that the procuring agency has clearly mentioned that the samples of medical devices and equipment will be tested, analyzed and evaluated by the committee. The same has been clearly mentioned in the bidding documents. The General conditions of contract describe the provision of samples.

When required, the Focal Person of the bidder will be informed on phone or through email to provide samples of the items in sufficient / required quantity for examination / analysis /expert opinion to the office of Central Procurement Committee, [CPC] Government of Sindh at bidder's own risk and cost at the time and date communicated. The samples will be non-returnable and no payment what so ever shall be payable to bidder / Focal Person on this account in the name of price/transportation charges etc.

29. The para mentioned above describes that the bidder will provide the samples in ample quantity for the examination, check, inspection, scrutiny and review of the quoted items. The aim, objective and need for the sample is required for the opinion of professionals, experts and technical persons of the procuring agency in order to ascertain that the procurement of these items bring value for money in terms of quality, timeliness, reliability, price, source, and above all quality to meet the procuring agency's requirements. Hence, the procuring agency has authority to evaluate the quoted items through samples irrespective of its certification, validation

and experience.

30. It was noted that the procuring agency has clearly mentioned that Evaluation and Disqualification criteria in the bidding documents.

Valid cGMP /Quality Control /Quality Assurance Certificate (attested from the embassy of the country of origin of the quoted item/s in Pakistan or Pakistani embassy in the country of origin). Non provision of the embassy attested certificate will lead to disqualification of firm.

ii. Availability of minimum 25% inventory of the total import of the quoted item/s during last one year (certificate to the effect duly signed by the senior executive of the firm & evaluated by the CPC expert/s). Non availability of the 25% stock at the time of inspection shall lead to disqualification of the quoted item/s.

iii. Adherence to Good Storage Practices (GSP) for finished goods storage of the quoted item/s. Non adherence to GSP, as evaluated by the CPC expert/s at the time of inspection as evaluated by the CPC expert/s, valid / current certificate duly attested by drug regulator shall lead to Disqualification of the firm. GSP certificate must attested by FID/Provincial Drug Inspector.

iv. Valid Free Sale certificate for the quoted item/s duly attested by the Pakistani embassy in the country of origin of quoted item/s or embassy of the country of origin in Pakistan. Non Provision of the embassy attested certificate shall lead to Disqualification of the quoted item/s.

v. Samples of devices will be tested and evaluated by the Drugs Testing Laboratory (DTL) as well as by the CPC expert/s and the quoted item/s shall be disqualified for further competition on their adverse report/s.

31. The above excerpted criteria make clear that along-with certification and other documents, the procuring agency will test and evaluate the samples and in case of **adverse report of such samples** the bidder will be disqualified for further competition. This evaluation criteria are mentioned in the bidding documents that was accepted by the bidder by submitting the bid. **Thus, the bidder has been disqualified in accordance with the terms and conditions mentioned in the bidding documents**. The same has been described under rules that all bids will be evaluated in accordance with the criteria mentioned in the bidding documents,

Evaluation of Bids

a. ***All bids shall be evaluated in accordance with the evaluation criteria and other terms and conditions set forth in the bidding documents;***

32. Mr. Riaz Hussain Soomro, Chairperson of the Review Committee was of the view that the Review Committee of SPPRA is intended to prevent the violation of any provision of the Act, any rule, regulation, order or instruction made there under or any other law in respect of, or relating to, public procurement. Furthermore, the Review Committee is authorized to check the discriminatory actions of the procuring agency and to ensure that procurements are conducted in a fair and transparent manner and the object of procurement brings value for money to the agency and the procurement process is efficient and economical. **It is purpose of the Review Committee to check whether choice or decision is made as per the Act and the rules therein and not to check whether choice or decision is "sound". Evaluating tenders and awarding contracts are essentially administrative and policy functions. The Review Committee cannot direct for formulating certain evaluation criteria and cannot intervene in the technical evaluation of products by the experts of the procuring agency. The sole purpose of the Review Committee is to ensure that the procurement has been done in accordance with the rules and no discrimination has been made among the bidder.** In the instant there is no breach of rules in evaluating the samples as per criteria mentioned in the bidding documents and **disqualifying the bidder due to the adverse results of the samples.**

Review Committee's Decision

33. Given the proceedings findings/observations and after due deliberation, the review committee, in exercise of statutory powers conferred upon it under Rule 32(7)(a) ibid read with Sub-Section (1) Section-2 of SPP act 2009, declares the instant review appeal dismissed and allows the procuring agency to continue the Procurement process as per Rules.

(Member)
Syed Adil Gilani
Private Member SPPRA Board
Representative Transparency International

(Member)
Engr. Munir Ahmed Shaikh
Independent Professional

(Member)
Manzoor Ahmed Memon
Member SPPRA Board

(Chairman)
Riaz Hussain Soomro
Managing Director
Sindh Public Procurement Regulatory Authority