REPUBLIC OF KENYA

PUBLIC PROCUREMENT ADMINISTRATIVE REVIEW BOARD

APPLICATION NO. 130/2020 OF 30TH SEPTEMBER 2020

BETWEEN

REVITAL HEALTHCARE (EPZ) LTD.....APPLICANT

AND

THE ACCOUNTING OFFICER,

KENYA MEDICAL SUPPLIES AUTHORITY.....RESPONDENT

LABNAL MEDICAL SOLUTIONS LIMITED.....INTERESTED PARTY

Review against the decision of The Accounting Officer, Kenya Medical Supplies Authority with respect to Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products.

BOARD MEMBERS

1. Ms. Faith Waigwa -Chairperson
2. Mr. Nicholas Mruttu -Member
3. Arch. Steven Oundo, OGW -Member

IN ATTENDANCE

1. Mr. Stanley Miheso -Holding brief for Secretary

BACKGROUND TO THE DECISION

The Bidding Process

Kenya Medical Supplies Authority (hereinafter referred to as "the Procuring Entity") advertised Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products (hereinafter referred to as "the subject tender"), in the Daily Nation Newspaper and the People Newspaper on 26th May 2020.

The Procuring Entity further vide a letter dated 2nd June 2020 which became part of the Tender Document as 'Clarification 1' informed all bidders that the volume for Item No. 3 should be 4ml and the volume for Item No. 4 should be 6ml.

Bid Submission Deadline and Opening of bids

A total of nineteen (19) firms/bidders submitted bids and the same were opened on 16th June 2020 in the presence of bidders and their representatives who chose to attend and which bids were recorded as follows:

Bidder No.	Bidder Name
1.	Caperina Enterprises Ltd
2.	Partec East Africa Ltd
3.	Lued Chemicals Ltd
4.	Highridge Pharmaceuticals Ltd
5.	Sciencescope Limited

Bidder No.	Bidder Name
6.	Ten Cent Agencies Limited
7.	Chemoquip Ltd
8.	Medionics Healthcare Ltd
9.	Overseas Technical Support Services Limited
10.	Ultralab E.A. Ltd
11.	Revital Healthcare (EPZ) Ltd
12.	Harley's Limited
13.	Sai Pharmaceuticals Limited
14.	Steplabs Technical Services Limited
15.	Labnal Medical Solutions Limited
16.	Surgipath Services East Africa Ltd
17.	Amiken Limited
18.	Phsiobase Pharmaceutical Kenya Ltd
19.	Ellen Barron Medical Centre Limited

Evaluation of Bids

The evaluation process was conducted in four stages:

1. Preliminary Examination
2. Technical Evaluation - Documents
3. Technical Evaluation - Product
4. Financial Evaluation

1. Preliminary Evaluation

At this stage of evaluation, documents submitted by bidders were subjected to an examination to confirm the following:

- Bid document was paginated
- Copy of Certificate of Incorporation was provided
- Copy of valid Tax Compliance Certificate was provided
- Tender form duly completed and signed
- Anti-corruption policy/Declaration of Undertaking duly signed
- Bid Bond was original.
- Bid Bond was valid for 150 days
- Value of bid bond was KES 625,200.00/-.
- Business questionnaire was duly completed and signed.

Upon conclusion of Preliminary Evaluation, three (3) bidders were disqualified from further evaluation for the following reasons: -

1. Bidder No 7 M/s Chemoquip Ltd –Tax Compliance Certificate was not provided.
2. Bidder No 12 M/s Harley's Limited –. Provided a low bid amount of Kshs 205,000.00/- instead of Kshs 625,200.00/-.
3. Bidder No 19 M/s Ellen Barron Medical Centre Limited- Its bid document was not paginated and tender form not duly completed.

Sixteen (16) bidders, that is Bidder No. 1,2,3,4,5,6,8,9,10,11,13,14,15,16,17 and 18 passed preliminary examination and qualified for the next stage of evaluation.

2. Technical Evaluation - Documents

At this stage of evaluation, documents submitted by bidders were subjected to a detailed examination to confirm the following:

- Manufacturers Authorization that is both tender and item specific. (**MANDATORY)**
- Current GMP/Certificate of Quality for products offered issued to the manufacturer by a recognized independent body (**MANDATORY)**

Bidders who failed to meet any of the above criteria were declared non-responsive and disqualified from further evaluation.

Item No.3 Vacutainer Blood Collecting Tube 4ml Glass EDTA-K

Requirements	Caperina Enterprises Ltd_1	Partec East Africa Ltd_2	Lued Chemicals Ltd-3	Highridge Pharmaceuticals Ltd-4	Sciencescope Limited_5	Ten Cent Agencies Limited_6	Medionics Healthacer Ltd-8
Current GMP/Certificate of Quality for products offered issued to the manufacturer by a recognized independent body	TUV Cert: G1094273003 Exp:26/05/2024	TUV Cert: Q50433240029 Exp:30/07/2022	TUV Cert: SX601464450001 Exp:20/02/2023	TUV Cert: Q60128252001 Exp:16/04/2021	TUV Rheinland SX: Q601380770001 Exp:05/04/2022	TUV Cert: G20863890013 Exp:08/04/2024	BSI (MD721115 Exp:7/04/2023
Manufacturers Authorization that	WEGO	Improve-Guangzhou	LDS labour system	CDRICH	Weihai Sunway Medical Ltd	Nanjing Superstar Medical	VONTUR-NIO LTD

Requirements	Caperina Enterprises Ltd_1	Partec East Africa Ltd_2	Lued Chemicals Ltd-3	Highridge Pharmaceuticals Ltd-4	Sciencescope Limited_5	Ten Cent Agencies Limited_6	Medionics Healthacer Ltd-8
is both tender and item specific)			GMBH				
Verdict	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Requirements	Revital Healthcare Ltd-11	Sai Pharmaceuticals Ltd-13	Steplabs Technical Services Limited_14	Labnal Medical Solutions Ltd-15	Surgipath Services East Africa-16	Amiken Ltd-17	Phsiobase Pharmaceuticals Ltd-18
Current GMP/Certificate of Quality for products offered issued to the manufacturer by a recognized independent body	Item was not in the scope of Quality Certificate	Item was not in the scope of Quality Certificate	ISO not within the scope	Shandong Chengwu Medical	UK Cert: UQ-4856 Exp:24/03/2022	TUV-SUD Q6178893226009 Exp:12/01/2021	ISO provided does not match to MA
Manufacturers Authorization that is both tender and item specific)	N/A	Revital Healthcare Ltd	TODOSCAN Shanghai Medical Co. Ltd	Shandong Chengwu Medical	Biotec (P) Ltd	Henso	MA provided does not have manufacturers information
Verdict	Fail	Fail	Fail	Pass	Pass	Pass	Fail

Upon conclusion of evaluation with respect to Item No. 3, Four (4) bidders were found non-responsive for the following reasons: -

a) Bidder No 11. (M/s Revital Healthcare Ltd)

1. Quality Certificate No. Q61052440001 (ISO 13485:2016) does not cover the product under its scope. The other ISO certificate provided 90001:2015 is a management system certificate.
2. The GMP No-QVC/GMP/2019-20/111 Provided only cites EDTAK3, K2(5ML,6ML)

b) Bidder No 13. (M/s Sai Pharmaceuticals Ltd)

1. Quality Certificate No. Q61052440001 (ISO 13485:2016) does not cover the product under its scope. The other ISO certificate provided 90001:2015 is a management system certificate.
2. The GMP No-QVC/GMP/2019-20/111 Provided only cites EDTAK3, K2 (5ML, 6ML)

c) Bidder No 14. (M/s Steplabs Technical Services Limited)

1. Item was not in the scope of Certificate of Quality provided

d) Bidder No 18. (M/s Phsiobase Pharmaceuticals Ltd)

1. Certificate of Quality provided did not match Manufacturers Authorization provided, that is, certificate is from Jiangsu Kangjie Co. Ltd while Manufacturers Authorization is from Sichuan Machinery Corporation.
2. Manufacturers Authorization provided did not contain manufacturers Details.

Eleven bidder(s), that is Bidder No. 1 M/s Caperina Enterprises Ltd, Bidder No. 2 M/s Partec East Africa Ltd, Bidder No 3. M/s Lued Chemicals Ltd, Bidder No. 4 M/s Highridge Pharmaceuticals Ltd, Bidder No. 5 M/s Sciencescope Limited, Bidder No 6. M/s Ten Cent Agencies Limited, Bidder No. 8 M/s Medionics Healthcare Ltd, Bidder No. 9 M/s Overseas Technical Support Services Limited, Bidder No. 15 M/s Labnal Medical Solutions Ltd, Bidder No. 16 M/s Surgipath Services East Africa and Bidder No. 17 M/s Amiken Ltd were found responsive and thus recommended for product evaluation of the item.

3. Technical Evaluation - Products

This stage of evaluation involved product evaluation, packaging evaluation and labelling evaluation. The evaluation was based on product type, product form i.e. the physical configuration and shape, product ingredients i.e. content, components and composition, measurements i.e. dimension and weight, elasticity where applicable, absorbency where applicable and texture where applicable.

The packaging criteria was based on whether the product was securely wrapped, quality of packaging material, unit package, individual package, presence of peel off sign and peel ability (ease of opening the package), presence of tamper-proof seal whereas the labelling criteria was drawn from the technical specifications spelt out in the Tender Document.

The evaluation was on a "Yes/No" basis. Products that did not meet the evaluation criteria were disqualified.

Upon conclusion of evaluation with respect to Item No. 3, the following four (4) bidders were found non-responsive in the product evaluation as follows: -

a) Bidder No 3. (M/s Lued Chemicals Ltd)

- Did not provide sample for evaluation of product

b) Bidder No 4. (M/s Highridge Pharmaceuticals Ltd)

- Manufacturers Authorization is from CD Rich whereas product is from Highcare.

c) Bidder No 6. (M/s Ten cent Agencies Ltd)

- Sample submitted was in packs of 50's instead of 100's

- Manufacturers details on the sample were not indicated

d) Bidder No 16. (M/s Surgipath Services Ltd)

- Did not provide sample for evaluation of product.

Samples from Bidder No. 1 M/s Caperina Enterprises Ltd, Bidder No. 2 M/s Partec East Africa Ltd, Bidder No. 5 M/s Sciencescope Ltd, Bidder No. 8 M/s Medionics Healthcare Ltd, Bidder No. 15 M/s Labnal Medicals Services Ltd and Bidder No. 16 M/s Amiken Ltd were found responsive in the product examination and therefore qualified for financial evaluation.

4. Financial Evaluation

The Evaluation Committee undertook financial evaluation as follows: -

Item No.3 Vacutainer Blood Collecting Tube 4ml Glass EDTA-K

#	Bidder Name	Initial Quantity	UOM	Unit Price (bidders Currency)	Exchange Rate	Unit price (Ksh)	Total Cost (Bidder's Currency)	Total Cost (Ksh)	Delivery Schedule
1	Carperina Enterprises Ltd	16,950	Pack of 100's	Kes 744.00	1	744.00	Kes 12,610,800.00	12,610,800.00	12 weeks
2	Partec East Africa Ltd	16,950	Pack of 100's	Usd 13.00	106.4912	1384.37	Usd 220,350.00	23,465,335.92	8-12 weeks
5	Sciencescope Ltd	16,950	Pack of 100's	Usd 6.24	106.4912	664.51	Usd 105,768.00	11,263,361.24	4-6 weeks
8	Medionics Healthcare Ltd	16,950	Pack of 100's	Usd 5.64	106.4912	600.61	Usd 95,598.00	10,180,345.74	8-12 weeks
15	Labnal Medical Solutions Ltd	16,950	Pack of 100's	Kes 597.00	1	597.00	Kes 10,119,150.00	10,119,150.00	10-11 weeks
17	Amiken Ltd	16,950	Pack of 100's	Usd 6.30	106.4912	670.89	Usd 106,785.00	11,371,662.79	8-12 weeks

Bidder Name	Total Cost After preference(Kes)	Domestic Pref	CR 12	Shareholding
Carperina Enterprises Ltd-1	11,349,720.00	10%	Yes	Kenyan
Partec East Africa Ltd-2	21,118,802.33	10%	Yes	Kenyan
Sciencescope Ltd-5	10,137,025.12	10%	Yes	Kenyan
Medionics Healthcare Ltd-8	9,162,311.17	10%	Yes	Kenyan
Labnal Medical	9,107,235.00	10%	Yes	Kenyan

Bidder Name	Total Cost After preference(Kes)	Domestic Pref	CR 12	Shareholding
Solutions Ltd-15				
Amiken Ltd-17	10,234,496.51	10%	Yes	Kenyan & Indian

The Evaluation Committee's Recommendation

In view of the evaluation process, the Evaluation Committee recommended award of the subject tender with respect to Item No. 3 to **M/s Labnal Medical Solutions Ltd** at a unit price of **Kshs 597.00/-** and at a total cost of **Kshs 10,119,150.00/-** for being the lowest evaluated responsive bidder.

Professional Opinion

The Acting Procurement Director reviewed the Evaluation Report and concurred with the Evaluation Committee's recommendation of award, vide a Professional Opinion dated 7th September 2020.

REQUEST FOR REVIEW NO. 130 OF 2020

M/s Revital Healthcare (EPZ) Limited, (hereinafter referred to as "the Applicant"), lodged a Request for Review dated 29th September 2020 and filed on 30th September 2020 together with a Statement in Support of Request for Review (hereinafter referred to as "the Applicant's Statement") dated 29th September 2020 and filed on 30th September 2020 through the firm of Gerivia Advocates LLP. The Applicant further filed a Further Statement dated 13th October 2020 on 14th October 2020 (hereinafter referred to as "the Applicant's Further Statement").

In response, the Procuring Entity lodged a Replying Affidavit sworn and filed on 9th October 2020 (hereinafter referred to as 'the Procuring Entity's Affidavit') through the firm of Anne Munene & Company Advocates.

The Applicant sought for the following orders in the Request for Review: -

a. ***An order annulling and setting aside the Respondent's decision awarding Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products to Labnal Medical Solutions Limited;***
b. ***An order annulling and setting aside the Respondent's decision communicated by the letter dated 16th September 2020 notifying the Applicant that it had not been successful in Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products;***
c. ***An order directing the Respondent to carry out a re-evaluation noting to observe and apply the criteria in the Tender Document objectively as required by the Act at section 80 (3);***
d. ***An order compelling the Respondent to pay to the Applicant the costs arising from and incidental to this application; and***
e. ***Any such and further orders as it may deem fit and appropriate in ensuring that the ends of justice are fully met in the circumstances of this Request for Review.***

On 16th March 2020, the Board issued Circular No. 1/2020 and the same was published on the Public Procurement Regulatory Authority (hereinafter referred to as "the PPRA") website (www.ppra.go.ke) in recognition of the challenges posed by COVID-19 pandemic and instituted certain measures to restrict the number of representatives of parties that may appear before the Board during administrative review proceedings in line with the presidential directives on containment and treatment protocols to mitigate against the potential risks of the virus.

On 24th March 2020, the Board issued Circular No. 2/2020 further detailing the Board's administrative and contingency management plan to mitigate COVID-19 pandemic. Through this circular, the Board dispensed with physical hearings and directed that all request for review applications be canvassed by way of written submissions.

The Board further cautioned all parties to adhere to the strict timelines as specified in its directive as the Board would strictly rely on documentation filed before it within the timelines specified to render its decision within twenty-one days of filing of the request for review in accordance with section 171 of the Public Procurement and Asset Disposal Act, No. 33 of 2015 (hereinafter referred to as "the Act").

The Request for Review was lodged on 30th September 2020. The Procuring Entity was then notified of the existence of the Request for Review by the Board Secretary vide a letter dated 28th September 2020.

Thereafter, emails were sent to all bidders who participated in the subject tender, including the successful bidder, that is, the Interested Party, on 15th October 2020. However, the Interested Party did not file any pleadings in response to the Request for Review.

The Applicant lodged Written Submissions dated 13th October 2020 on 14th October 2020 whereas the Procuring Entity lodged Written Submissions on 19th October 2020. The Interested Party did not file any Written Submissions.

BOARD'S DECISION

The Board has considered each of the parties' cases, the documents filed before it, including confidential documents filed in accordance with section 67 (3) (e) of the Public Procurement and Asset Disposal Act, 2015 (hereinafter referred to as "the Act") together with parties' written submissions.

The issue that arises for determination is as follows: -

> **Whether the Procuring Entity found the Applicant's bid non-responsive at the Technical Evaluation – Documents Stage in accordance with section 80 (2) of the Act as read together with Article 227 (1) of the Constitution with respect to the following criterion in the Tender Document: -**

a) Current GMP/Certificate of Quality for products offered issued by a recognized independent body (MANDATORY)

A brief background to the Request for Review is that the Procuring Entity advertised the subject tender on 26th May 2020 and invited interested and eligible bidders to submit bids in response to the same.

By the bid submission deadline of 16th June 2020, the Procuring Entity received a total of nineteen (19) bids which were opened and read out by the Procuring Entity's Tender Opening Committee in the presence of bidders and their representatives.

At the conclusion of the evaluation process, the Procuring Entity's Evaluation Committee recommended award of the subject tender to M/s Labnal Medical Solutions for having the lowest evaluated responsive bid which recommendation of award was approved by the Procuring Entity's Accounting Officer, having been reviewed by the Head of Procurement function. The successful bidder including all unsuccessful bidders, were duly notified of the outcome of their bids.

The Applicant contended in paragraph 5 of its Request for Review that vide a letter dated 16th September 2020, it was informed by the Procuring Entity that its bid was unsuccessful for the following reasons: -

Item No.	***Item Description***	
3	***Vacutainer Blood Collecting Tube 4ml Glass EDTA -K***	***1. Quality Certificate No. Q61052440001 (ISO 13485:2016) does not cover the product under its***

		scope ***2. The ISO certificate provided 90001:2015 is a management systems certificate.*** ***3. The GMP No. QVC/GMP/2019-20-/111 Provided only cites EDTAK3, K2 (5ml, 6ml)***

Aggrieved by the Procuring Entity's decision, the Applicant lodged the instant Request for Review.

The Applicant contended that it submitted the required certifications and documentation from pages 27 to 31 of its bid document, in compliance with the mandatory technical requirements in the Tender Document and thus argued that the Procuring Entity failed to evaluate the Applicant's bid in accordance with its own criteria in the Tender Document, section 80 (2) and (3) of the Act read together with Article 227 (1) of the Constitution.

On its part, the Procuring Entity submitted that the certifications and documentation provided by the Applicant in its bid document did not demonstrate that the item to be supplied by the Applicant met the requirements of manufacturing legislation and regulations of health products set in the country of origin as required under the Tender Document. The Applicant was therefore found non-responsive at the Technical Evaluation of Documents Stage and disqualified from further evaluation.

Having considered parties' pleadings and written submissions, the Board examined the Procuring Entity's Tender Document and observes that the subject tender is *'For the Supply of Blood Transfusion Products'* inferring that the tender in question is for the procurement of goods/products.

The Board studied the Procuring Entity's Tender Document in order to determine what documentary evidence including certifications with respect to the subject goods/products, were required from bidders under the subject tender.

The Board observes that Clause 6 'Documents Establishing Eligibility of Goods and Services and Conformity to Tender Documents' of Section I Instructions to Tenderers provides as follows: -

> ***"6.1 Pursuant to ITT Clause 14, the Tenderer shall furnish as part of its tender, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and Services to be supplied under the contract."***
>
> ***6.2 The documentary evidence of the eligibility of the goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered that shall be confirmed by a Certificate of Origin, issued shortly before the time of shipment.***

6.3 The documentary evidence of conformity of the Goods and Services to the Tender Documents may be in the form of literature, drawings and data and shall consist of:

a) <u>a detailed description of the essential technical and performance characteristics of the goods</u>…." **[Emphasis by the Board]**

Further, Clause 14. 1 (e) Documents Constituting the Tender of Section I Instructions to Tenderers provides as follows: -

"The tender submitted by the Tenderer shall comprise the following:

d)……;

(e) documentary evidence establishing to the Purchaser's satisfaction and in accordance with ITT Clause 6 that the goods and ancillary services to be supplied by the Tenderer are eligible goods and services pursuant to ITT Clause 5 and that they conform to the Tender Documents."

Also, Clause 6.3 (c) (a) Instructions to Tenderers of Section II Tender Data Sheet on page 27 of the Tender Document provides as follows: -

"Documentation and sample requirements for eligibility of the offered goods.

In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b) the following shall be included with the tender:

(a) <u>Documentary evidence demonstrating that the goods meet the requirements of manufacturing legislation and regulation of health products in the country of origin</u>" **[Emphasis by the Board]**

In view of the foregoing provisions, the Board observes that bidders were required to provide as part of their bid documents, documentation establishing the eligibility of the goods to be supplied under the subject tender, and documentation that demonstrates that the said goods meet the requirements of manufacturing and regulation of health products in the country of origin.

This is in line with Clause 5.1 (a) Standards of Quality Assurance for Supply under Section V 'Specifications' on page 59 and 60 of the Tender Document which provides as follows: -

"All products must:

a) Meet the requirements of manufacturing legislation and regulation of Non-pharmaceutical and medical products in the country of origin;

b) Be certified by a competent authority in the manufacturer's country according to "World Health Organization Certification Scheme on the Quality of Medical Products Moving in International Commerce"

c) Conform to all the specifications contained herein."

Further, the Board observes Clause 6.4 (a) Instructions to Tenderers of Section II Tender Data Sheet on page 28 of the Tender Document provides as follows: -

> ***"The product should conform to KEBS/ISO Standards or equivalent"***

Notably, the Tender Document does not expressly stipulate what amounts to an equivalent of the KEBS/ISO Standards.

The Board examined the evaluation criteria outlined in the Tender Document with respect to the Technical Evaluation of Documents as contained in Section VIII Evaluation Criteria on page 97 and 98 of the Tender Document which reads as follows: -

> ***"B) Technical Evaluation***
>
> *1. Bidders who are Manufacturers*
>
> ***Documents submitted by manufacturers offering to supply items under the Contract will be subjected to a detailed examination to confirm the following:***
>
> ***a) Current GMP/Certificate of Quality for products offered issued by a recognized independent body (MANDATORY)***
>
> ***NOTE: Failure to comply with Mandatory Requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation***

2. *Bidders who are Distributors*

Documents submitted by Distributors offering to supply products under the Contract will be subjected to a detailed examination to confirm the following:

a) Current GMP/Certificate of Quality for products offered issued to the manufacturer by a recognized independent body (MANDATORY)

b) Manufacturer's Authorization that is tender and item specific (MANDATORY)"

NOTE: Failure to comply with Mandatory Requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation."

Accordingly, bidders who were manufacturers were required to submit a '*Current GMP/Certificate of Quality for products offered issued by a recognized independent body*' whereas bidders who were distributors were required to provide the said certificate in addition to a '*Manufacturer's Authorization that is tender and item specific'*. Further, failure to comply with this mandatory requirement would lead to disqualification from further evaluation.

The Procuring Entity furnished the Board with the nineteen (19) original bids submitted to it by bidders as part of its confidential file with respect to the subject tender in accordance with section 67 (3) (e) of the Act.

The Board examined the Applicant's original bid and observes from the Applicant's Form of Tender on page 10 therein that the Applicant offered to supply and deliver '*Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping sample collection'*.

Further, on page 6 of its bid document, the Applicant submitted an Export Processing Zone Enterprise Licence valid until 20th March 2021 licensing the Applicant to manufacture *interalia* blood collection tubes.

In this regard therefore, the Applicant was a licensed manufacturer with respect to the subject tender and was thus required to provide a '*Current GMP/Certificate of Quality for products offered issued by a recognized independent body*' pursuant to the aforementioned criterion in the Tender Document.

The question that now arises is what is a 'Current GMP/Certificate of Quality for products'?

The Black's Law Dictionary defines the term 'Certificate' as: -

"a written assurance or official representation that some act has or has not been done or some event occurred or some legal formality has been complied with."

A certificate is therefore a written assurance or official representation demonstrating the occurrence of an event, performance or non-performance of an act or compliance with a legal formality.

According to the International Certifications website www.intlcert.com, GMP is an abbreviation for the term 'Good Manufacturing Practice'. The website states that Good Manufacturing Practice (hereinafter referred to as 'GMP') is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any production that cannot be eliminated through testing the final product.

Moreover, GMP covers all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff. GMP guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that a food or drug product is safe for human consumption.

The Board further studied www.isoupdate.com which is a website that provides information, resources and updates around the Standards and Certification industry and notes that GMP is described as a system of processes, procedures, and documentation that help ensure that products are consistently produced and controlled according to quality

standards. These practices are required in order to conform to guidelines and regulations recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products.

Further, GMP applies to organizations that manufacture and process drugs, cosmetics, medical products, and food and GMP certification is granted to manufacturing or service systems of organizations to certify that they engage with good manufacturing practices in their manufacturing or service processes, according to a Standard Code of Practice related to their business.

According to the said website, many countries have legislated that food, pharmaceutical and medical device manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation.

On the other hand, a Certificate of Quality or what is commonly referred to as 'product certification' or 'product qualification' is defined by CEOpedia Management Online as

> ***"a process when certain product has reached certificate; After product has passed performance tests and quality assurance tests and also meets qualification criteria which are counted in contracts, specifications and regulation"***

A Certificate of Quality is therefore a written assurance or official representation that a product has passed performance tests and quality assurance tests and meets certain qualification criteria.

Turning to the instant case, the Board has established that the Applicant was required to provide a '*Current GMP/Certificate of Quality for products offered issued by a recognized independent body*' pursuant to the aforementioned mandatory technical criterion in the Tender Document.

As mentioned hereinbefore, the Applicant submitted a bid to supply and deliver '*Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping sample collection'* identified as Item No. 3 under the subject tender.

Specifications for this item, that is Item No. 3 were provided under Product Specifications on page 72 and 73 of the Tender Document as follows:

> ***"Item No. 3 Vacutainer tubes with EDTA for blood grouping***
>
> ***Description:*** *For sample collection blood grouping specimen with EDTA anticoagulant*
>
> ***Product Parameters:***

- *K3 vacuum plastic purple tops tubes*
- *Volume: 4mls*
- *Size 12x75 mm*
- *Contains EDTA anticoagulants*

Packaging

Pack of 100 pieces

Standard weight of carton should be less or equal 20kg

Labelling parameters

- *Should be in English and in indelible ink*
- *User instructions and storage conditions indicated*
- *All packaging labelled with GOK – MOH during delivery*
- *Each carton to be clearly marked with name characteristics of the article and number of units per carton*
- *Manufacturers name and address, Country of Origin, Batch No., Date of manufacture and expiry*
- *Product should have a minimum of 75% remaining shelf life at the time of delivery*
- *Should conform to KEBS/ISO standard or equivalent*
- *Manufacturer must be KEBS/ISO standard or equivalent*

In this regard therefore, the Applicant was required to provide a Current GMP or a Certificate of Quality issued by a recognized independent body for Item No. 3 as specified in the Tender Document, that is, '*Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping*'.

The Board examined the Applicant's original bid and observes that the Applicant provided the following documentation in response to this criterion: -

On page 0022 of its original bid, the Applicant provided a KEBS Certificate 'Permit to Use The Standardization Mark' with Standardization Mark No. 12982. The Board observes from the said certificate that it was issued by KEBS to the Applicant on 1st April 2020 and is effective from 23rd May 2020 to 22nd May 2021. The said certificate provides a description of the commodity upon which the standardization mark is to be used as 'Blood Collection Tube' and a Standard Specification of KS ISO 6710 Kenya Standard for Single Use – Containers for venous Blood Specimen Collection.

In order to determine whether or not this certificate was a Current GMP/Certificate of Quality for the product in question, that is, Item No. 3 as specified under the Tender Document, the Board finds it necessary to determine the meaning and import of a KEBS Certificate 'Permit to Use Standardization Mark'.

The Board studied the Standards Act, Chapter 496, Laws of Kenya (hereinafter referred to as 'the Standards Act') and notes that section 3 thereof establishes the Kenya Bureau of Standards (hereinafter referred to as 'KEBS'). According to section 4 (1) of the Standards Act, two key functions of KEBS is "**to promote standardization in industry and commerce**" and "**to control, in accordance with the provisions of this Act [the Standards Act], the use of standardization marks and distinctive marks**".

Section 2 of the Standards Act further defines a "Kenya Standard" as: -

> ***"a specification or code of practice declared under section 9(1)"***

The meaning of a standardization mark is explained under section 2 thereof as ***"a mark which has been specified by the Council under section 10"*** whereas section 10 goes further to state as follows: -

> ***"The Council shall, by notice in the Gazette, specify a separate mark, to be known as a standardization mark, for each of the following purposes—***
>
> ***(a) application to any commodity which is the subject of an order under section 9(2); and***
>
> ***(b) application to a commodity which is not the subject of an order under section 9(2) but concerning the manufacture or sale of which the Council has approved as specification."***

The said Section 9 (2) provides as follows:

> ***"Where a Kenya Standard has been declared under subsection (1), the Minister, on the advice of the Council, shall, by order in the Gazette, prescribe a date after which no person shall manufacture or sell any commodity, method or procedure to which the relevant specification or code of practice relates unless it complies with that specification or code of practice."***

In view of the above provisions of the Act, the Board examined the KEBS website at www.kebs.org and notes that KEBS is the premier government agency for the provision of Standards development, Conformity Assessment, Training and Certification services in Kenya.

KEBS, through its Kenya Bureau of Standards Certification Body (KEBS CB) issues various certifications including KEBS Standardization Mark, KEBS Mark of Quality and also Quality Management System certification based on the ISO 9001 standard.

The Board further notes that KEBS Standardization Mark is a mandatory product certification scheme for locally manufactured products provided for under section 10 of the Standards Act. To acquire the mark, manufactured goods are expected to meet quality requirements as specified in the various Kenya/Approved Standards. A permit to use a

Standardization Mark is issued to a firm by KEBS to certify that a particular product conforms to requirements in a Standard.

Turning to the instant case, the Board observes that the KEBS Certificate 'Permit to Use Standardization Mark' provided by the Applicant did not outline the specifications of the product certified therein and thus the product certified under the Applicant's KEBS Certificate did not meet the parameters and the specifications for the product to be manufactured and supplied by the Applicant, that is, Item No. 3 as outlined in the Tender Document.

In this regard therefore, it is the Board's considered view that the said KEBS Certificate did not demonstrate the quality of the product to be supplied by the Applicant, this being Item No. 3 whose specifications are clearly outlined in the Tender Document. It therefore follows that the Applicant's KEBS Certificate did not amount to a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document.

Accordingly, it is the finding of this Board that the Applicant's KEBS Certificate 'Permit to Use The Standardization Mark' as contained on page 0022 of its original bid did not satisfy the mandatory technical criterion as provided in the Tender Document.

Moving forward, on page 0023 - 0024 of the Applicant's original bid, the Applicant provided a document titled 'Medical Device Certificate' issued to the Applicant by the Ministry of Health Pharmacy and Poisons Board, valid until 31st December 2020 for approval to supply a product described as 'CADY Blood Collection Tube'.

From an examination of the said certificate, the Board observes that the same is a certificate for approval for the Applicant to supply 'CADY Blood Collection Tube' but is neither a Current GMP or a Certificate of Quality demonstrating the quality of the item to be supplied by the Applicant, that is, Item No. 3, as specified under the Tender Document.

Further, the said certificate did not outline the specifications of the product that the Applicant was approved to supply, that is, 'CADY Blood Collection Tube' and thus it is not possible to ascertain whether the said product meets the specifications of Item No. 3 as outlined in the Tender Document.

It therefore follows that the Applicant's 'Medical Device Certificate' did not amount to a Current GMP or a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document.

Accordingly, it is the finding of this Board that the Applicant's 'Medical Device Certificate' as contained on page 0023 - 0024 of its original bid

did not satisfy the mandatory technical criterion as provided in the Tender Document.

The third document for consideration in the Applicant's bid was provided on page 0025 - 0026 of its bid, that is, Certificate No. 19 0068 SJ/a issued by one 'Management Systems Certification Body Institute for Testing and Certification, Inc' to the Applicant on 3rd June 2020 and valid until 30th October 2022.

The said certificate confirms that the Applicant has '*implemented and documented a functional quality management system in compliance with the requirements of the standard EN ISO 9001: 2015*, covering the scope of activities that the certificate applies to as described in the Annexure attached to the certificate, which includes the Development, Manufacturing and Export of blood collection tubes.

In order to determine whether this certificate meets the mandatory technical criteria in the Tender Document, it is imperative for the Board to determine the meaning and import of an ISO Standard.

According to the official ISO website, www.iso.org, ISO (International Organization for Standardization) is an independent, non-governmental international organization which brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to

global challenges. These international standards give world-class specifications for products, services and systems, to ensure quality, safety and efficiency.

From the ISO official website, the Board notes that ISO 9001 is an international standard that sets out the requirements for a quality management system and helps businesses and organizations to be more efficient and improve customer satisfaction.

The Board further notes that the ISO 9001 standard is updated and reviewed regularly and ISO 9001:2015 is one of the versions of the ISO 9001 standard which specifies the requirements for a quality management system that an organization must maintain in their system in order to be issued with an ISO 9001:2015 certificate.

Turning to the instant case, the Board is of the considered view that the certificate provided by the Applicant on page 0025 - 0026 of its bid was a management system certificate which did not certify or demonstrate the quality of the product to be supplied by the Applicant, that is Item No. 3, as described in the Tender Document.

Further, the said certificate did not outline the specifications of the product certified therein and thus it is not possible to ascertain whether the said product meets the specifications of Item No. 3 as outlined in the Tender Document.

It therefore follows that the said certificate did not amount to a Current GMP or a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document.

Accordingly, it is the finding of this Board that the Applicant's Certificate No. 19 0068 SJ/a on page 0025 - 0026 of its original bid did not satisfy the mandatory technical criterion as provided in the Tender Document.

Fourthly, the Applicant on page 0027 of its original bid provided a certificate titled 'QVC Certificate No. QVC/CE/IVD/2019-20/112', issued by one QVC Certification Services Pvt Limited to the Applicant on 25th October 2019 with an expiry date of 24th October 2022. According to the said certificate, the product in vitro diagnostic medical devices **Blood Collection Tube** as manufactured by the Applicant, complied with the applicable essential requirements of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

Further, an annexure to the said certificate provided the following specifications for the blood collection tube as follows:

"EDTA K3 – 13x75mm, Size 2ml, 3ml and 4ml"

The question that arises in this regard is what is a QVC Certificate or QVC Certification?

According to the QVC Certification Services Pvt Limited website www.qvccert.com, the said company which is based in India, offers certification and technical services in the field of *interalia* Product Certifications. The said company provides accredited certification services through its alliance partner, ITC (Institute for Testing and Certification) based in Czech Republic, Europe.

As stated in their website, the accreditation certification services serve as a guarantee of independent and objective high-grade services and is the standard of the technical competence of the workplace.

The Board notes, the said certificate as provided by the Applicant in its bid document confirmed that the product identified as a blood collection tube with the specifications **"EDTA K3 – 13x75mm, Size 2ml, 3ml and 4ml"** manufactured by the Applicant complied with the applicable essential requirements of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

However, the Procuring Entity in its Written Submissions argued that although the aforesaid certificate provided the specifications of the product, the same was only in respect of vacutainers containing EDTA for blood grouping which are manufactured in India. It was therefore the Procuring Entity's submission that since the Vacutainers containing EDTA for blood grouping were manufactured in Kenya the QVC Certificate from India could not demonstrate that the Vacutainers

containing EDTA for blood grouping met the requirements of manufacturing legislation and regulation of health products set in Kenya.

The Board notes, although QVC Certification Services Pvt Limited which issued the Applicant's QVC Certificate in issue is based in India, the said company offers *interalia* product certification services in conjunction with its alliance partner, ITC (Institute for Testing and Certification) based in Czech Republic, Europe and in accordance with the relevant requirements of Council Directive 98/79/EC, which in essence are standards developed for the European Union for in vitro diagnostic medical devices.

Notably, the Procuring Entity in its Tender Document required bidders to provide documentary evidence that the goods meet the requirements of manufacturing legislation and regulation of health products in the country of origin. Further, the Procuring Entity required products to be supplied with respect to the subject tender to conform to KEBS/ISO Standards or their equivalent.

As mentioned hereinbefore, the Procuring Entity's Tender Document does not expressly stipulate what amounts to an equivalent of the KEBS/ISO Standards.

In its determination of this issue, the Board perused the Interested Party's original bid and observes on page 74 therein, that the Interested

Party submitted a document titled 'EC Declaration of Conformity Regarding In Vitro Diagnostic Directive (98/79/EC)' which document confirms that the product to be manufactured by the Interested Party's Manufacturer, that is, one Shandong Chengwu Medical Products Factory, conforms to *interalia* the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC)'.

The Board notes that these standards are the same standards referred to in the Applicant's 'QVC Certificate No. QVC/CE/IVD/2019-20/112' and yet the Interested Party's document titled 'EC Declaration of Conformity Regarding In Vitro Diagnostic Directive (98/79/EC)' was determined to have satisfied the mandatory technical criterion in issue whereas the Applicant's QVC Certificate was rejected on this basis, which in the Board's view runs contrary to the public procurement principle of fairness as espoused under Article 227 (1) of the Constitution as follows: -

> ***"When a State organ or any other public entity contracts for goods or services, it shall do so in accordance with a system that is fair, equitable, transparent, competitive and cost-effective." [Emphasis by the Board]***

Article 227 (1) of the Constitution recognizes fairness as one of the principles that guide public procurement processes in Kenya. This therefore means since the Applicant and the Interested Party submitted documents with respect to the same standard, they ought to have been

treated the same way during evaluation to promote the public procurement principle of fairness.

Moreover, the Board has established that the Applicant's QVC certificate outlined the specifications of the product certified therein and thus it is possible to ascertain from the said certificate the quality of the product to be manufactured and supplied by the Applicant under the subject tender and that the said product meets the specifications of Item No. 3 as outlined in the Tender Document.

The Board therefore finds that the Applicant's 'QVC Certificate No. QVC/CE/IVD/2019-20/112' amounts to a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document and thus satisfies the mandatory technical criterion as outlined in the Tender Document.

The fifth documentation submitted by the Applicant as found on page 0029 of the Applicant's bid is titled 'QVC Certificate WHO GMP Compliance Verification No. QVC/GMP/2019-20/111' issued to the Applicant by QVC Certification Services Pvt Limited on 25th October 2019 and set to expire on 24th October 2021.

The said certification indicates that the Applicant fulfilled the requirements applicable to it as per the WHO GMP Guidelines for

certification scope of "Manufacture and Supply of Syringes, Needles, Infusion therapy product, Catheters and Tubes".

Further, an Annexure to the said certification provides a detailed description of the scope of the product certified as follows: -

"Blood Collection Tubes

EDTA K3 – 13X100mm (5ml, 6ml)"

It is not disputed by the Procuring Entity that the said certificate is on the face of it a GMP Certificate issued by QVC Certification Services Pvt Limited pursuant to the WHO GMP Guidelines.

However, the Board observes that the scope of the product as stipulated in the said certificate does not capture the specific parameters of the product to be supplied by the Applicant, that is, Item No. 3, noting that the specifications for Item No. 3 as outlined in the Tender Document are **EDTA K3 – 12x75mm, Size 4ml** whereas the specifications provided in the said certificate are ***EDTA K3 – 13X100mm (5ml, 6ml).***

In this regard therefore, the Applicant's 'QVC Certificate WHO GMP Compliance Verification No. QVC/GMP/2019-20/111' certificate provided on page 0025 - 0026 of the Applicant's original bid did not amount to a Current GMP or a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document.

Accordingly, it is the finding of this Board that the Applicant's 'QVC Certificate WHO GMP Compliance Verification No. QVC/GMP/2019-20/111' certificate provided on page 0025 - 0026 of the Applicant's original bid did not satisfy the mandatory technical criterion as provided in the Tender Document.

Finally, the Applicant on page 0032 - 0034 of its original bid, submitted a Certificate No. Q6 105244 0001 Rev. 00, issued to the Applicant by DAkks, a German Company, valid from 17th April 2020 until 15th August 2022, with Certification Mark TUV SUD Product Service Gmbh. The said certificate indicated the Applied Standard(s) as EN ISO 13485:2016; Medical Devices – Quality Management Systems Requirements for Regulatory purposes (ISO 13485: 2016) DIN EN ISO 13485: 2016) and that the scope of the certificate is the 'Manufacturing and distribution of *interalia* transfusion set (blood administration set)'.

Further, the certificate indicated that the Applicant has implemented a quality assurance system for manufacture and final inspection of the devices indicated in the said certificate.

The Board notes that the said certification demonstrates that the Applicant has put in place a quality management system in compliance with the requirements of the standard, that is, EN ISO 13485:2016; Medical Devices – Quality Management Systems Requirements for

Regulatory purposes (ISO 13485: 2016) DIN EN ISO 13485: 2016) to manufacture the products covered in the certification scope.

However, the said certification does not demonstrate the quality of the product to be manufactured and supplied by the Applicant, that is Item No. 3, as specified in the Tender Document. Further, the products covered in the scope of the said certification do not meet the parameters and specifications for the product to be manufactured and supplied by the Applicant, that is Item No. 3, as outlined in the Tender Document.

In this regard therefore the Applicant's Certificate No. Q6 105244 0001 Rev. 00 does not satisfy the mandatory technical criterion as indicated in the Tender Document.

In totality of this issue, the Board finds that the Procuring Entity did not find the Applicant's bid non-responsive at the Technical Evaluation – Documents Stage in accordance with section 80 (2) of the Act read together with Article 227 (1) of the Constitution, noting that the Applicant's 'QVC Certificate No. QVC/CE/IVD/2019-20/112' amounts to a Certificate of Quality for Item No. 3, that is, 'Vacutainer tubes 4ml with EDTA anticoagulant for blood grouping' as specified in the Tender Document and thus satisfies the mandatory technical criterion as outlined in the Tender Document.

In view of this finding, the Board finds it necessary to direct the Procuring Entity to re-admit the Applicant's bid at the Technical Evaluation – Documents Stage and conduct a re-evaluation of the Applicant's bid in accordance with the provisions of the Tender Document, section 80 (2) of the Act read together with Article 227 (1) of the Constitution, taking into consideration the findings of the Board herein.

Accordingly, the Board finds that the Request for Review Application succeeds with respect to the following specific orders: -.

FINAL ORDERS

In exercise of the powers conferred upon it by section 173 of the Public Procurement and Asset Disposal Act, 2015, the Board makes the following orders in the Request for Review: -

1. **The Accounting Officer of the Procuring Entity's Letter of Notification to Enter into a Contract with respect to Item No. 3 in Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products dated 16th September 2020 addressed to M/s Labnal Medical Solutions Limited be and is hereby cancelled and set aside.**

2. **The Accounting Officer of the Procuring Entity's Letters of Notification of Unsuccessful Bid with respect to Item No. 3 in Tender No. KEMSA/ONT 02/2020-2022 For Supply of Blood Transfusion Products dated 16th September 2020 and addressed to all unsuccessful bidders, including the Applicant herein, be and are hereby cancelled and set aside.**

3. **The Accounting Officer of the Procuring Entity is hereby directed to re-admit the Applicant's bid at the Technical Evaluation – Documents Stage and conduct a re-evaluation of the Applicant's bid together with all other tenderers at the Technical Evaluation – Documents Stage in accordance with section 80 (2) of the Act read together with Article 227 (1) of the Constitution, taking into consideration the**

findings of the Board herein, with respect to the following mandatory technical criterion on page 97 and 98 of the Tender Document: -

a) Current GMP/Certificate of Quality for products offered issued by a recognized independent body (MANDATORY)

4. **Further to Order No. 3 above, the Accounting Officer of the Procuring Entity is hereby directed to proceed with the procurement process to its logical conclusion within fourteen (14) days from the date of this decision.**

5. **Each party shall bear its own costs in the Request for Review.**

Dated at Nairobi, this 21st Day of October 2020

CHAIRPERSON **SECRETARY**

PPARB **PPARB**