**PUBLIC PROCUREMENT ADMINISTRATIVE REVIEW BOARD**

**APPLICATION NO. 28 OF 2017 DATED 13TH MARCH, 2017**

**BETWEEN**

**QUESTA CARE LIMITED..... (APPLICANT)**

**AND**

**KENYA MEDICAL SUPPLIES AUTHORITY..... PROCURING ENTITY**

**SIMBA PHARMACEUTICALS LIMITED.....INTERESTED PARTY**

Review against the decision of the Kenya Medical Supplies Authorityin the matter of Tender No. KEMSA/GOK-CPF/HIV-16/17- OIT 001 for the supply and delivery of ARV medicines - adults.

**BOARD MEMBERS PRESENT**

1. Mr. Paul Gicheru - Chairman
2. Mr.Hussein Were - Member
3. Mr. Peter B. Ondieki, MBS - Member
4. Mrs.Rosemary Gituma - Member

**IN ATTENDANCE**

1. Stanley Miheso - Holding Brief for Secretary
2. Evelyn Abuga - Secretariat

**PRESENT BY INVITATION**

**Applicant – Questa Care Limited**

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|---|---|
| 1. Peter Njeru | - Advocate, Kaplan & Stratton |
| 2. Benjamin Ng'eno | - Advocate, Kaplan & Stratton |
| 3. Hiran Mehta | - Director, Questa Care Ltd. |
| 4. Abhay Walvekar | - Ex Director |
| 5. Reubenson Mugo | - GM QA/RA |
| 6. Sandreep Rathod | - Lawyer,Mylan Laboratories |

**Procuring Entity – Kenya Medical Supplies Authority**

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|---|---|
| 1. Julius Migos Ogamba | - Advocate, Migos-Ogamba Advocates |
| 2. Ong'anda Junior | -Advocate,Migos-Ogamba Advocates |
| 3. Alex Musyoki | - Lawyer, Migos-Ogamba Advocates |
| 4. Miller Mageto | -Lawyer, Migos-Ogamba Advocates |
| 5. Fredrick Wanyonyi | - DMS/CS |
| 6. Charles Juma | - Director Procurement |
| 7. David Nuttu | -Procurement Manager |
| 8. John Kabuchi | - Procurement Manager |
| 9. Edward Buluma | -Procurement Manager |
| 10.Caroline Mugo | - Procurement officer |
| 11.Martin Ekitele | - Procurement officer |
| 12.Anthony Chege | - Procurement officer |

**Interested Parties**

| | |
|---|---|
| 1. Waweru Gatonye | - Advocate, Simba Pharmaceuticals |
| 2. Charles Gatonye | - Advocate |
| 3. Jamila Yesho | - Lawyer |
| 4. Isssack Abdullahi | - Pupil |
| 5. Ravi Menon | - CEO, Simba Pharmaceuticals |
| 6. Naresh Kumar | - Director, Simba Pharmaceuticals |
| 7. J.P. Joshua Prabhu | -Country Manager, Aurobindo Pharm |

## BOARD'S DECISION

Upon hearing the representations of the parties and the interested party before the Board and upon considering the information and all the documents before it, the Board decides as follows;

## BACKGROUND OF AWARD

The National AIDS and STI Control Program received an allocation under Counterpart Financing for the procurement of Program commodities valued at Kshs. 2,128,172,314.00 for the FY 2016/2017.

The procurement request was received from the National Treasury vide letter Ref No. EA/FA/240/107/ (5) dated **13th September, 2016.**

The funds to meet this procurement have been set aside in the budget at an estimated sum of **Kshs 1,126,950,699.00**

This was an Open International Tender for procurement of **ARV Medicine-Adult.** The tender was subjected to the requirements of Sections 96, 97 and 98 of the Act.

The Tender was advertised in two dailies: the Standard News Paper on **11th October, 2016** and the Star on **13th October, 2016** and was to close/open on **24th November, 2016.**

However, an extension of the closing date was granted which was published in the Standard Newspaper of **18th November, 2016** with a new closing date of **8th December, 2016**. The extension was occasioned by a clarification sought by a prospective bidder and a response was made vide Clarification No. 1 dated 1st November, 2016. Subsequently, the Chief Executive Officer approved the extension vide an email dated **15th November, 2016**. The extension was granted Pursuant to Section 75(5) of the Public Procurement and Asset Disposal Act (PPADA) 2015

A total of **Seven (7)** Bidders submitted their bids.

The Evaluation Committee was constituted on an ad hoc basis, on **23rd December, 2016** vide letter **Ref: KEMSA/PROC-CPF/HIV/OIT 001/16** and comprised of Five(5) members and a secretary to oversee the evaluation process which carried out the process from **4th January, 2017** and completed the exercise on **6th January, 2017.**

The Chief Executive Officer reviewed the professional Opinion from the

head of procurement and the evaluation report from the tender processing committee on Tuesday 17th January, 2017 for Tender No. KEMSA/GOK-CPF/HIV-16/17-OIT-001 - for supply and delivery of ARV medicines – Adults and made an award as per the Professional Opinion and the recommendations of the evaluation committee.

Notification letters were subsequently sent to all bidders on **19th January, 2017**.

On **27th January, 2017** KEMSA received an appeal No. 10 of 2017 to the Public Procurement Administrative Review Board by M/s Questa Care Limited disputing the ground that led to it's bid being declared non-responsive.

On **16th February, 2017**, the Board delivered the following decision on the said request for review:-

- ***The decision of the procuring entity awarding Tender No. KEMSA/GOK-CPF/HIV – 16/17 – OIT 001 for the supply and delivery of ARV medicine – Adults to the successful bidder Simba Pharmaceuticals Limited is hereby annulled.***
- ***The applicant is allowed back into the evaluation process and the procuring entity is directed to evaluate the applicant's technical and financial bids.***
- ***In evaluating the applicants financial bid, the procuring entity is directed to give the applicant preference as prescribed under part XII***

*of the Public Procurement and Assets Disposal Act 2015 which prescribes the grant of preferences and reservations under the Act.*

**2.0 Authority to Re-Evaluate Procurement Process**

Following the above orders, the Ag. Chief Executive Officer vide a memo dated **23rdFebruary, 2017**authorised the Evaluation Committee to reconvene and re-evaluate the tender as ordered by the Public Procurement & Administrative Review board.

The evaluation process was carried out in two stages as directed by Public Procurement & Administrative Review board.

a) Technical Evaluation.
    i) Documentary Compliance of the Tenderer.
    ii) Technical Evaluation of the Product (Sample)
b) Financial Evaluation.

**3.0 Technical Evaluation of documents**

Seven (7) bidders were considered for technical evaluation of documents based on the evaluation criteria set out in the tender document this was done on an item by item basis.

- Item 1: Five (5) bidders bided for this item; One (1) bidder no. 3 was disqualified, while Four (4) bidders' no. 1, 2, 4 and 6 were recommended to proceed to the next stage of evaluation.

- Item 2: Two (2) bidders bided for this item; both bidders' no. 5 and 7were recommended to proceed to the next stage of evaluation.

**3.1 Technical Evaluation of products**

Six (6) bidders were considered for technical evaluation of products based on the evaluation criteria set out in the tender document.

- Item 1: All four (4) bidders' no. 1, 2, 4 and 6were recommended to proceed to financial evaluation.
- Item 2: Both bidders' no. 5 and 7were recommended to proceed to financial evaluation.

**3.2 Financial Evaluation.**

The evaluation committee recommended the award per item to the lowest evaluated responsive bidder.

**Observations**

The evaluation committee applied domestic preference and reservations to the four (4) bidders as outlined at page 55 of the tender document.

**Item 1**

Bidder No. 1: Cipla limited

- The bidder did not qualify for any preference because they are a foreign firm offering product manufactured in India.

Bidder No. 2: Simba Pharmaceuticals limited

- The bidder was granted 10% margin of preference under clause 4Cbecause they are 100% Kenyan owned Company.

Bidder No. 4: Sai Pharmaceuticals Limited

- The bidder was granted 10% margin of preference under clause 4C because they are 100% Kenyan owned Company.

Bidder No. 6: Questa Care Laboratory Limited.

The bidder was eligible to 10% Preference on two fronts;

a) The bidder is 100% Kenyan owned Company and was eligible to 10% preference under clause 4C.
b) The bidder has a contractual arrangement with a foreign firm Mylan Laboratories Limited of India thus was eligible to 10% under clause 5.

The bidder was therefore granted 10% preference.

**Note:** From the documents submitted, the bidder was not granted 15% margin of preference because it was alleged that the item was not fully manufactured in Kenya.

**4.0 Recommendation for Award**

Based on the above, the Tender Processing Committee recommended, the tender to be awarded as below; as it was determined to be substantially responsive and the lowest evaluated tenderer for the item(s).

| Item No. | Item Description | Unit of Issue | Quantity | Unit Price (Usd) | Total Price (Usd) | Awarded Supplier |
|---|---|---|---|---|---|---|
| 1. | Tenofovir300 mg/Lamivudine 300mg/Efavirenz 600mg Tablets | Pack of 30's | 1,500,001 | 6.75 | 10,125,006.75 | **Simba Pharmaceuticals Limited** |

The prices realized are within the market price.

**PROFESSIONAL OPINION**

The Director Procurement vide his letter to the accounting officer dated 1st March, 2017 opined that , , the tender be awarded as below; M/s Simba Pharmaceuticals Limited for the supply and delivery of Tenofovir300mg/ Lamivudine 300mg/Efavirenz 600mg Tablets with unit of issue Pack of 30's Quantity 1,500,001 Unit Price (Usd) 6.75 at the Total cost of USD 10, 125,006.75.

He stated that the prices realized were within the market.

**THE REQUEST FOR REVIEW**

This Request for Review was lodged by Questa Care Limited on 13th March, 2017, against the decision of the Kenya Medical Supply Authority dated 19th January, 2015 in matter of tender No. **KEMSA/GOK-CPF/HIV-16/17- OIT 001** for the supply and delivery of ARV Medicines – Adults.

During the hearing of the Request for Review, the Applicant was represented by Mr. Peter Njeru while the procuring entity was represented by Mr. Julius Ogamba Migosi. The successful bidder M/s Simba Pharmaceuticals Limited was on the other hand represented by Mr. Waweru Gatonye Advocate.

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

1. *The decision of the Procuring Entity awarding Tender No. KEMSA/GOK - CPF/HIV - 16/17 - OIT 001 for the supply and delivery of ARV Medicines - Adults to the successful bidder be annulled.*
2. *The decision in respect of the award for Tender No. KEMSA/GOK - CPF/HIV - 16/17 - OIT 001 for the supply and delivery of ARV Medicines - Adults be substituted by the Review Board's decision that the Applicant's bid for the supply and delivery of ARV Medicines – Adults, is successful.*
3. *Alternatively, the Procuring Entity be directed to re-evaluate the Applicant's financial bid applying the 15% margin of preference reserved for goods manufactured in Kenya, in accordance with the Law and the criteria set out in the Tender document.*
4. *The costs of this request for review be awarded to the Applicant.*

## THE ARGUMENTS

Mr. Peter Njeru counsel for the Applicant relied on the request for review dated 13th March 2017. He stated that this was the second request for review that was being filed arising from the tender for the supply and delivery of ARV drugs for adults. Mr. Njeru stated that on 27th January, 2017 vide application number 10 of 2017, the applicant filed a request for review after the procuring entity declined to award the tender to it on the basis that the site indicated on the label was an office address and not a

manufacturing site. Mr. Njeru further submitted that the initial request for review, the Board delivered its determination where it found among other things that the procuring entity could not use a criteria other than the one set out in the tender document in evaluating the tender and further that the Applicant was entitled to preference.

Mr. Njeru additionally submitted that the issue as to whether the applicant was a manufacturer or not was dealt with conclusively by the Board in application No.10 of 2017. He stated that the Board's decision in that respect was never challenged in the High Court and still stands. Mr. Njeru argued that the procuring entity had admitted in paragraphs 18, 26 and 27 of its replying affidavit that the applicant was involved in packaging, among other things, which he stated forms part of the manufacturing process. Mr. Njeru argued that having established that the applicant was a manufacturer and the respondent having admitted that fact, the Applicant was entitled to 15% preference as provided for by the Public Procurement (Preference and Reservation Regulations) 2011.

Counsel for the Applicant however submitted that in the re-evaluation process that followed after the decision of the Board in application number 10 of 2017, the procuring entity reviewed the applicant's bid and by a letter dated 1st March, 2017, the applicant was notified that it's financial proposal was unsuccessful and the

only reason stated by the procuring entity was that the Applicant's financial proposal for the item was not the lowest evaluated price after applying a 10% margin of preference. Counsel for the applicant argued that the decision by the procuring entity was not only ill conceived and malicious but done with a view of denying the applicant the award of the said tender. He stated that the procuring entity's decision contravened the law, the tender document and the decision of the Board delivered on 10th February 2017.

Counsel for the applicant further argued that it was not in dispute that the provisions relating to what margin of preference would be applicable was governed by part XII of the public procurement and asset disposal act, 2015, the Regulations and the tender document specifically at page 55. The applicant contended that it was entitled to a 15% margin of preference and not 10%. Mr. Njeru stated that the Applicant was entitled to a fifteen percent margin of preference in it's evaluated price since it was a candidate offering goods manufactured in Kenya as defined by law. He stated that the regulations also set out two other margins of preference that would be applicable and also set out the circumstances under which these other margins of preference would be applicable. Mr. Njeru argued that the applicant would be entitled to more than one scheme of preference. The first scheme of preference would be a 15% percent margin of preference in the evaluated price of tender for having goods manufactured in Kenya. The second margin of preference was a 10% margin, which would also be applicable to the applicant for

having a share holding of Kenyan Citizenship of more than 51% and the third Margin of preference that would be applicable is a ten percent margin of preference for having entered into a contractual relationship with a foreign contractor.

Mr. Njeru further argued that it was very clear that the Procuring Entity knew that these three schemes of preference might raise challenges and that is why the tender document provided that a bidder shall only be entitled to one scheme of preference and that where a bidder was entitled to more than one scheme, the scheme with the highest advantage to the bidder would apply. It is on that basis therefore that the Applicant felt entitled to a 15% margin of preference.

Mr. Njeru further argued that pursuant to Section 156 of the Act and Regulation 18 of the public procurement (Preference and Reservation Regulations) 2011, where a candidate was entitled to more than one preference scheme, the scheme with the highest advantage to the tenderer would apply. The question that needed to be answered according to Mr. Njeru was on what basis the procuring entity refused to apply the 15% margin of preference in favour of the applicant.

Mr. Njeru argued that the only reason that had been cited by the procuring entity as a reason which the applicant discovered via the replying affidavit and which was never stated in the letter of

notification, or in the tender document and which had no basis in law was that the ARVs were not wholly manufactured in Kenya and the applicant was therefore not entitled to the preference margin reserved for goods manufactured in Kenya.

Mr. Njeru finalized his submissions by stating that the Board had held repeatedly that evaluation and comparison of tenders should be done using the procedures and the criteria set out in the tender document and that a procuring entity cannot use a criteria other than the one set out in the tender document. Mr Njeru stated that Section 155(3) of the Act clearly provides that preference shall be given to manufactured articles, materials and supplies partially mined or produced in Kenya or where applicable have been assembled in Kenya. Mr. Njeru argued that even if there was a requirement that the 15% margin of preference would only apply to goods that had been wholly manufactured in Kenya, the Applicant would still have been entitled to rely on the provisions of Section 155(3) of the Act which recognizes and makes it mandatory for preference to be applied even to goods that have not been wholly manufactured in Kenya. Counsel for the applicant further argued that there was no doubt that the applicant had been licensed as a manufacturer by the Pharmacy and Poisons Board which is the only entity in Kenya empowered to issue the license. Mr. Njeru finalized his submissions by saying that under the Provisions of Section 3 of the Public Procurement and Asset Disposal Act, one of the principles guiding public procurement was the promotion of

local industry and that the successful bidder which was awarded the tender by the Procuring entity imports readymade and fully packaged goods at a cost that is almost similar to that of the applicant which is doing part of the manufacturing in the country. Mr. Njeru argued that the successful bidder did not have a manufacturing licence but only had a distributorship licence and thus could not benefit from the same margin of preference as the Applicant. He argued that it was therefore improper for the procuring entity to have introduced a criteria that was not set out anywhere in the tender document in denying the applicant the tender. He asked the Board to find that the Procuring entity had failed to evaluate the bids in accordance with the criteria set out in the tender document contrary to the Provisions of Section 80(1) and (2) of the Act and prayed that the application be allowed with costs.

Mr. Julius Ogamba counsel for the procuring entity opposed the Applicant's request for review and firstly stated that the board never found in application for review number 10 of 2017 that the applicant was a manufacturer. He stated that the Board in fact never gave a finding with respect to the question of whether or not the applicant was a manufacturer. He therefore stated that the Applicant's contention in that regard was not true.

On the Provisions of Section 155(3) of the Act, Mr. Ogamba argued that Section 155(3), as it stood, could not be applied. He stated that

Section 155(5) stipulates the circumstances under which a bidder can be granted preference for goods that are produced or partially produced in Kenya. He stated that Section 155(5) states that where a Procuring Entity seeks to procure items not wholly or partially manufactured in Kenya, the accounting officer shall cause a report to be prepared detailing evidence of inability to procure manufactured articles, materials and supplies wholly mined or produced in Kenya and (b) that the procuring entity shall require a successful bidder to cause technological transfer or create employment opportunities as shall be prescribed in the Regulations. Mr. Ogamba however stated that those regulations are not in place. He therefore argued that subsection 155(3) which the applicant sought to rely upon was therefore inapplicable and was not available to it.

Mr. Ogamba, further argued that it was clear from the license from the Pharmacy and Poisons Board what the applicant was licensed to do. Mr. Ogamba argued that the applicant was not actually manufacturing a finished product. He also stated that it was not in dispute that the applicant was approved by WHO to package the product but the product it was packaging was a finished product that belonged to another organization namely M/s Mylan Laboratories Ltd India. He argued that it was not possible that the Applicant produces the ARVs in Kenya. Mr. Ogamba further submitted that out of the nine stages of manufacturing, the Applicant was only doing one part namely, packaging, and that the

other eight stages were being done in India. He argued that the applicant could not be deemed a manufacturer of that product in this country by dint of the definition under the Income Tax Act that includes packaging as part of manufacturing. He stated that the only way that one could allocate packaging to be part of manufacturing is if the product had a continuous line in one place belonging to one company. He submitted that that is when one could say packaging is part of that exercise. He however strongly opposed the contention that packaging standing alone could be defined as manufacturing.

Mr. Ogamba reiterated his written submissions and referred the Board to the case of ***Mjengo Ltd =vs= The Commissioner of Income Tax (2016) eKLR*** in support of the proposition that packaging alone cannot amount to manufacturing. Mr. Ogamba stated that the applicant wanted a mischievous interpretation and application of the act in order to benefit from a preference that it was not entitled to. He stated that it was not in dispute that the applicant was a fully owned Kenyan company and further that it was not in dispute that the agreement between Mylan laboratories ltd and the Applicant was the basis of the Applicant submitting documents to the procuring entity for the tender.

Mr. Ogamba argued that the applicant on one hand was saying that it had a relationship with a more qualified person who was producing the products and on whose technology it was relying

upon while on the other hand it was stating that it was independent and a Kenyan manufacturer and therefore entitled to a 15% margin of preference.

On the issue of preference, Mr. Ogamba argued that that was dealt with in the tender document. He argued that it was not true to say that the procuring entity did not apply the criteria stipulated in the tender document. He argued that the tender document stated that the procuring entity shall grant exclusive preference to local contractors offering goods wholly manufactured in Kenya (National Reservation). He additionally stated that where goods are not wholly manufactured in Kenya, then the citizen and local contractors would not enjoy exclusive preference.

Mr. Ogamba further argued that clause 4(c) of the tender document stated clearly that 10% preference of the evaluated price of the tender would be awarded to a shareholder where the percentage of shareholding of Kenyan citizens was more than fifty percent and that where citizen contractors had entered into contractual arrangements with foreign contractors, a ten percent margin of preference in the evaluated price of the tender shall be applied. So for both, being a Kenyan citizen and entering into an agreement with a foreign contractor, you are entitled to 10% preference which was what was granted to the Applicant and thus there was no conflict at all.

Mr. Ogamba, also argued that the applicant had 15 employees compared to India's Mylan Laboratories Ltd which employed 30,000 people proving the applicant was not a manufacturing firm and was thus not assisting Kenyans get jobs. He prayed that the application be dismissed with costs.

Mr. Waweru Gatonye who appeared on behalf of the successful bidder opposed the applicant's request review and in so doing relied on three documents.

The first document was the affidavit sworn by one Kilithodi Ravinder Menon on 23rd March 2017, the second document was his submissions dated 27th March 2017 and the third document was a list of bundle of authorities dated 27th March 2017. Mr. Gatonye adopted every argument that had been presented by Mr. Ogamba in opposition to the request for review. In his submissions, Mr. Gatonye said there was truly only one issue before the Board and that issue was whether the applicant was a manufacturer within the meaning of the Act.

Mr. Gatonye argued that the ruling given by the Board on 16th February 2017 in the request for review No.10 of 2017 did not make a determinition that the applicant was a manufacturer. According to Mr. Gatonye, the Board only found that the applicant firm was

wholly owned by Kenyans. He stated that this was far from making a finding that the applicant was a manufacturer.

Mr. Gatonye argued that what the board decided was that the applicant was a Kenyan registered firm bearing a registration number CPR/2013/117151'. He stated that the board also never stated the percentage of preference that the Applicant was entitled to since that was a function of the Procuring Entity based on the law. The Board also stated that, the financial evaluation in the first instance was the duty of the procuring entity.

Mr. Gatonye further argued that the issue of whether a tenderer was a manufacturer or not was a question of mixed law and fact but it was important to note that there was no definition of a manufacturer under the Act. Mr. Gatonye while referring to the Provisions of Sections 155 and 156 of the Act submitted that it did not matter what the tender document stated and averred that any Provision in the tender document could not superceed the provisions of the law which in his opinion stipulated that a person claiming a 15% margin preference had to establish that he/it had was a full manufacturer of the goods regarding which it was seeking the said margin of reference.

Mr. Gatonye argued that a partial manufacturer of goods is actually not the true manufacturer of the goods in question. He submitted

that the Applicant had misread the Provisions of Section 155(3) of the Act. He further submitted that a careful perusal of the Provisions of Section 155 of the Act, there were two categories of preference for manufacturers, one being where the goods were wholly produced in Kenya and was covered by subsection 2 and going by the subsidiary legislation the margin of preference was 15%. He argued that for goods that are partially manufactured in Kenya, the category was different. He argued that Section 155(5) stated that *where a procuring entity seeks to procure items not wholly or partially manufactured in Kenya, the accounting officer shall cause a report to be prepared detailing evidence of inability to procure manufactured articles, materials and supplies wholly mined or produced in Kenya.*

He therefore stated that there was thus a distinction between the Provisions of Sections 155(3) and Section 155(5) of the Act and that Section 155(3) was inapplicable to the circumstances of this case as no Regulations had been made as envisaged by the Provisions of Section 155(5) of the Act so as to bring the Provisions of Section 155(3) of the Act into operation.

Mr. Gatonye argued that the Applicant's Nairobi site was not licensed for goods manufactured by the Applicant herein but for goods manufactured by Mylan Laboratories Ltd. He further argued that the products produced were manufactured to completion in India, by a foreign company and the only thing that happened in

Nairobi was packaging. He argued that the stand alone activity of packaging could not qualify a tenderer as manufacturer. He further argued that the Board must be careful because a holding that packaging amounts to manufacturing, would negate the noble objectives of the Public Procurement and Asset Disposal Act and Article 227 of the Constitution especially on the issue of creation of employment and technological transfer.

Mr. Gatonye made a brief reference to the case of ***Mjengo Ltd vs Commissioner of Domestic Tax (2016) eKLR*** where he stated that the court had decided that packaging alone did not amount to manufacturing.

In conclusion Mr. Gatonye, submitted that the Applicant's case must fail for two reasons. One was that there was no finding by the Board that the Applicant was a manufacturer in the request for review number 10 of 2017 and secondly because the Applicant was not a manufacturer within the meaning of the law. Mr. Gatonye therefore prayed that the Applicant's request for review be dismissed with costs to the successful bidder.

Mr. Njeru in a short reply to the submissions made by counsels of the procuring entity and the successful bidder stated that it had a licence to manufacture drugs for sale .He said the licence had been issued by the Pharmacy and Poisons Board pursuant to

provisions of the Pharmacy and Poisons Act. He invited the Board to look at Section 2 of the Pharmacy and Poisons Act as to the definition of who a manufacturer was. He stated that manufacturing included packaging of medical products and infact it talked about any process carried out in the course of making a product or medical substance and included packaging, blending, mixing, assembling and distillation. He argued that all those were covered in the term manufacturer and it is on that basis that the applicant was issued with a licence to manufacture drugs by the Pharmacy and Poisons Board which is the body that is mandated to issue such licenses. The other law that defined who a manufacturer was is the Income Tax Act at Section 24(3)e. He stated that the definitions in the two statutes were consistent with the definitions in the WHO Expert Committee on Specification of Pharmaceutical products.

Mr. Njeru further submitted that the public procurement and asset disposal act does not define who a manufacturer is. He stated that the applicant was a manufacturer within the provisions of Pharmacy and Poisons Act, the Income Tax Act and the WHO good manufacturing practices for pharmaceutical products: main principles a copy of which was annexed to this submissions.

In reply to the submissions made by counsel for the procuring entity that there cannot be manufacturing if there is no continuous

line, Mr. Njeru argued that no authority had been submitted to support that argument and that the argument cannot be upheld where there are clear provisions of the law that define what manufacturing is.

In reference to the case of ***Mjengo Ltd =vs= The Commissioner of Income Tax (2016) eKLR*** Mr. Njeru argued that the case was irrelevant and inapplicable to the circumstances of this case. He argued that the case related to rice and that rice was not regulated under any statute but medical products belonged to a highly regulated industry and the effect of the licence to manufacture issued by the Pharmacy and Poisons Board to the applicant is that the applicant would be held responsible for the batch release of the products it was licensed to finally release to the market.

Mr. Njeru argued that the technical agreement between the applicant and Mylan Laboratories Ltd was an internal document and did not in any way negate the status of the applicant as a manufacturer.

He concluded his submissions by stating that if at all the procuring entity intended that goods that are not wholly manufactured in Kenya would not be eligible to attract the 15% margin of preference, then there was nothing that would have stopped it from clearly stating so in the tender document. He instead stated that the tender

document was elaborate and clear and it was therefore wrong for the procuring entity to now come and try to introduce a criteria that was not set out in the tender document. He therefore invited the Board to hold that the applicant was a manufacturer as recognized by the Pharmacy and Poisons and the Income Tax Act. He stated that once the Board arrived at the decision that the applicant was a manufacturer, then automatically the applicant would be entitled to a 15% margin of preference.

During the course of the hearing of the request for review, the Applicant called one Dr. Reubenson Mugo the Head of Quality Assurance and Regulatory Affairs at the Applicant firm who took the Board through the processes which the product the subject matter of this request for review undergoes before it is released into the market. Both Counsel for the procuring entity and counsel for the successful bidder cross-examined Dr. Mugo but at the conclusion of the said exercise Dr. Mugo confirmed that the only process that the Applicant undertakes is the package of the ARV Products which are the subject matter of this request for review.

## THE BOARD'S DEICISON

The Board notes that the current Request for Review is a follow up of the Board's decision in Request for Review No. 10 of 2017 in which the Board held that the Applicant who was also the Applicant in Request for Review

No. 10 of 2017 was entitled to preference under the provisions of the Public Procurement and Asset Disposal Act and the Public Procurement and Disposal (preference and Reservations Regulations) 2011 which prescribe for the grant of preference and reservations.

Upon the delivery of the Board's decision in Public Procurement Administrative Review Application number 10 of 2017, the procuring entity in an apparent compliance with the said decision which was not the subject matter of any judicial review application or an appeal before the High Court embarked upon the process of both technical and financial evaluation and awarded both the successful bidder and the Applicant a 10% margin of preference in their financial bids of USD 10,125,006.75 and USD 10,500,007 respectively.

The Applicant however contested the margin of preference of 10% granted to it and instead argued that it was entitled to a margin preference of 15% which would have resulted in it's evaluated price being the lowest and would have therefore resulted in it being declared the lowest evaluated bidder.

The basis for the Applicant's contention was that it was a manufacturer and that in it's decision delivered on 16th February, 2017 in application number 10 of 2017 the Board had determined that it was a manufacturer and was therefore entitled to a preference of 15% of it's tendered price.

Counsel for both the procuring entity and the successful bidder however contested the basis of the Applicant's request for review and stated that the Board had not made a determination stating that the Applicant was a manufacturer and further that from the documents availed both to the procuring entity and the Board did not evidence that the Applicant was a manufacturer but showed that the Applicant instead undertook the packaging, storage and labeling of the subject drug on behalf of it's principal M/s Mylan Laboratories Ltd.

The only question that the Board needs to answer is therefore whether the Applicant is a manufacturer by virtue of undertaking the processes of packaging, storage, and labeling so as to make it a manufacturer within the meaning of the law so be as to entitled to a preference of 15% instead of 10% that was awarded to it by the procuring entity.

It was common ground by the Applicant, the procuring entity the successful bidder and from the evidence of Dr. Reubenson Mugo who gave evidence on behalf of the Applicant that the Applicant was only engaged in the process of packaging, storage and labeling of the HIV/AIDS, TB and Malaria commodities which it would have obtained from Mylan Laboratories Ltd in India. The procuring entity conceded that fact in paragraph's 26, 27 and 28 of it's replying affidavit sworn by Mr. Philip Omondi on 20th March 2017where the procuring entity stated as follows:-

26: **"That from the foregoing and other information contained in the bid supplied to the Respondent by the Applicant, it was evident that the product tendered for was manufactured by Mylan Laboratories Limited from India and pursuant to a technical/quality agreement between the Applicant and Mylan, the Applicant only undertook the packaging, storage and labeling requirements on behalf of its principal – Mylan Laboratories Limited**

27: **"That accordingly, the product was not wholly manufactured in Kenya. The active pharmaceutical ingredient (API) manufacturer is Mylan Laboratories Limited from India and the packaging site is the Applicant"**

28: **"That therefore the Applicant was entitled to enjoy a margin of preference of 10% as provided for by the law and the tender document as detailed under appendix 1 provided for domestic preference and reservations and in the conditions iv (c) or v".**

In order to answer the question framed above, the Board needs to determine whether a firm which engages in the process of packaging, storage and labeling of producers manufactured by a third party can fit the description of a manufacturer. In order to answer this question, the Board has gone through various statutes and the World Health Organization (WHO) good manufacturing practices for pharmaceutical products; main principles which give the definition of a manufacturer.

Section 2 of the pharmacy and poisons Act which is described as an Act of Parliament to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons describe a manufacturer as follows:-

> **"Manufacture "means any process carried out in the course of making a product or medicinal substance and includes packaging, blending, mixing, assembling, distillation, processing, changing of form or application of any physical process in the preparation of a medicinal substance or product, but does not include dissolving or dispensing the produce by diluting or mixing it with some other substances used as a vehicle for administration".**

Section 3(e), (v) of the income Tax Act (Cap 470) of the laws of Kenya describes a manufacturer for the purposes of the said Act as follows:-

**"Manufacturer "means the making (including packaging) of goods or materials from raw or partly manufactured materials or other goods or the generation of electrical energy for supply to the national grid but does not extend to any activities which are ancillary to manufacture, such as design, storage, transport or administration".**

While the World Health Organization good manufacturing practices for pharmaceutical products: Main principles on the other hand describe a manufacturer as follows:-

**"Manufacturer "A company that carries out operations such as production, packaging, repackaging, relabeling of pharmaceuticals".**

The Board has looked at all the above definitions and is of the view that any legal person (whether a company or an individual) which carries on the business of packaging, storage and labeling is a manufacturer within the provisions of the law and is entitled to a 15% percentage of preference.

The Board has also perused the provisions of the Public Procurement and Disposal Regulations (Preference and Disposal Regulations) 2011 and finds that the Applicant was entitled to the benefit of preference as a locally registered company and also as a manufacturer and whereas the first class of preference made it entitled to a preference margin of 10%, the second class of preference made is entitled to a preference of 15%. The Board therefore finds that under the provisions of the Act and the above cited Regulations, the Applicant was entitled to a percentage of preference which was most beneficial to it namely 15% preference.

During the hearing of the Request for Review both Counsel for the procuring entity and the successful bidder relied on the case of **Mjengo Limited -vs- The Commissioner of Domestic Taxes (2016)eKLR** for the proposition that packaging alone could not amount to manufacturing. The Board has read the said decision and finds that the same is distinguishable

from the present case in that the said decision was dealing with the issue of rice whereas the present case deals with the issue of drugs which is almost exclusively dealt with and regulated by the provisions of the pharmacy and poisons Act and the World Health Organization good manufacturing practices for pharmaceutical products. The Act and the World Health Organization good manufacturing practices for pharmaceutical products; main principles recognize packaging as part of manufacturing.

Based on all the foregoing facts and considerations, the Board therefore holds that the Applicant is entitled to a 15% margin of preference and the procuring entity therefore erred in failing to accord the Applicant the said margin of preference.

Consequently the Applicant's Request for Review is allowed and the Board makes the following orders on this Request for Review.

## FINAL ORDERS

In view of all the above findings and in the exercise of the powers conferred upon it by the Provisions of Section 173 of the Public Procurement and Asset Disposal Act 2015, the Board makes the following orders on this Request for Review:

1. **The Applicant's Request for review dated 13th March, 2017 is hereby allowed.**

2. The procuring entity is hereby directed to apply a 15% margin of preference against the price tendered for by the Applicant.

3. That the procuring entity shall carry out the financial re-evaluation of the Applicant's and successful bidder's financial bids in compliance with order 2 above and complete the same within a period of Fourteen (14) days from today's date.

4. Inview of the nature of the orders made above, the Board orders that each party shall bear it's own costs of this Request for Review.

Dated at Nairobi on this 3rd day of April, 2017.

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CHAIRMAN

PPARB

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SECRETARY

PPARB