PUBLIC PROCUREMENT ADMINISTRATIVE REVIEW BOARD

APPLICATION NO. 57 / 2011 OF 28TH DECEMBER, 2011

BETWEEN

FAMY CARE LIMITED.....APPLICANT

AND

KENYA MEDICAL SUPPLIES AGENCY.....PROCURING ENTITY

Review against the decision of the Tender Committee of Kenya Medical Supplies Agency dated 19th December 2011 in the matter of Tender No. KEMSA/OIT60/2011-2013 for the Supply of Family Planning Commodities.

BOARD MEMBERS PRESENT:

Mr. P.M. Gachoka	-	Chairman
Mrs. Loise Ruhiu	-	Member
Ms. Natasha Mutai	-	Member
Ms Judith A. Guserwa	-	Member
Mr. Sospeter Kioko	-	Member

IN ATTENDANCE:

Mr. C. R. Amoth	-	Secretary
Ms. Pauline Opiyo	-	Secretariat
Ms. Maureen Kinyundo	-	Secretariat

PRESENT BY INVITATION:

Applicant –Famy Care Limited

Mr. Muriuki Mugambi	-	Advocate
Ms. Muthoni Ndulwi	-	Lawyer
Mr. Navin Jansari	-	Manager, Marketing
Mr. Sasi Kumar	-	Vice President

Procuring Entity – Kenya Medical Supplies Agency

Mr. Fred Wanyonyi	-	Director, Legal Services
Mr. Charles Ezekiel	-	PD
Mr. John Kabuchi	-	PM
Dr. Kuria N.S.	-	DRH
Dr. Gathari Ndirangu	-	RH Technical Advisor

Interested Parties

Mr. Julius Ogamba	-	Advocate, Angelica Medical Supplies
Mr. Eliud Senten	-	Pupil (M & O), for Angelica Medical Supplies
Dr. Larry Kamamia	-	Pharmacist, Angelica Medical Supplies
Mr. Willy Soriney	-	Director, Pfizer International Corporation
Ms. Mary Matu	-	Executive Director, Angelica Medical Supplies
Ms. Irene Ibutu	-	Logistics Manager, Angelica Medical Supplies
Mr. D. Mathenge	-	General Manager, Hartwood Limited
Mr. Vinoo Gumptan	-	Sales & Marketing Director, Harleys Limited
Mr. Constance Oyugi	-	Tender Secretariat, Nairobi Enterprises Ltd
Mr. Antony Mugodo	-	Advocate, PAL International

BOARD'S DECISION

Upon hearing the representations of the parties and interested candidates and upon considering the information in all the documents presented before it, the Board decides as follows:

BACKGROUND OF AWARD

Advertisement:

The tender was advertised on 12th September 2011 in the Daily Nation and the Standard newspapers. In response to the advertisement, twenty-seven (27) prospective bidders bought tender documents. Closing date/time was 18th October, 2011 at 10 a.m.

Closing/Opening:

Closing / Opening of tenders was conducted on 18th October, 2011 at 10.00 a.m. Out of the twenty-seven (27) firms to whom tender documents were issued, sixteen (16) submitted their bids by closing time. All bidders' representatives present were given copies of the summary of the Tender Opening Minutes.

EVALUATION

The tenders were subjected to evaluation in two stages namely technical and financial evaluation.

Technical Evaluation

The evaluation process was divided into three stages:

- Preliminary Examination
- Evaluation of documents
- Evaluation of Products

Preliminary Examination

Sixteen bidders' documents were received for evaluation as detailed below:

Bidder No. 1 (Angelica Medical Supplies)

Bidder No. 2 (Winston International Ltd)

Bidder No. 3 (Biodeal Laboratories Ltd)

Bidder No. 4 (Nairobi Enterprises Ltd)

Bidder No. 5 (Bliss Gvs Pharma Ltd)

Bidder No. 6 (C. Mehta & Co. Ltd)

Bidder No. 7 (Royter Investments Ltd)

Bidder No. 8 (Surgilinks Ltd)

Bidder No. 9 (Ecolat Medical Supplies)

Bidder No. 10 (Harleys Ltd)

Bidder No. 11 (PAL International)

Bidder No. 12 (A One Healthcare Ltd)

Bidder No. 13 (York Investments E.A. Ltd)

Bidder No. 14 (Beijing Holley Cotec Ltd)

Bidder No. 15 (Hartwood Enterprises)

Bidder No. 16 (Famy Care International)

Documents submitted by the bidders were subjected to a preliminary examination to confirm the following:

- Tender form duly completed and signed
- Bid Bond is original.
- Value of bid bond is 2% of bid amount
- Bid Bond is valid for 120 days
- Business questionnaire is duly completed.
- Declaration of undertaking is signed
- Copy of Certificate of Incorporation is provided
- Copy of Current Tax Compliance is provided
- Copy of VAT Registration certificate is provided
- Copy of Pin Certificate is provided

Technical Examination – Documents (Pharmaceutical Drugs)

Documents submitted by the bidders were subjected to a detailed examination to confirm the following:

- Tenderer has a Good Distribution Practice (GDP) certificate/ Wholesale dealer's /Manufacturing license from Pharmacy & Poison's Board.
- Certificate of Superintendent Pharmacist Provided.
- Manufacturer's Authorization Given.
- Good Manufacturing Practice (GMP) certification.
- Registration Status.
- Manufacturing site for drugs is dedicated to the manufacture of hormonal products only.

Technical Examination - Documents (Non Pharmaceutical Items)

Documents submitted by the bidders were subjected to a detailed examination to confirm the following:

- Manufacturer's Authorization given
- Certificate of quality provided

Technical Evaluation - Product

The technical evaluation involved the product evaluation, packaging evaluation and labeling evaluation, using a checklist that had been developed and agreed prior to the evaluation exercise. The evaluation was based on the organoleptic properties of the products and packaging criteria was based on Good Manufacturing and pharmaceuticals practices of the particular dosage form , while the labeling criteria was drawn from the technical specifications spelt out in the tender documents.

The evaluation was on a "Yes/No" basis; with a "Yes" score earning one point and a "No" score earning no point (0). The scores for each item bid were represented as a percentage of the maximum possible score for that item on a weighted score as follows:

- Product Evaluation – 80%
- Labeling and Packaging Evaluation – 20%

Products that were not registered or did not meet the set 100% of the set product evaluation criteria were disqualified. Products were required to meet at least 75% of the labeling requirements, giving a minimum weighted average score of 95%.

Suppliers who were successful at the examination of documents stage and had products that had a minimum weighted technical score of 95% were recommended for financial evaluation.

Table of Findings - Preliminary Examination

Bidder	**1 (Angelica Medical Supplies)**	**2 (Winston International Ltd)**	**3 (Biodeal Laboratories Ltd)**	**4 (Nairobi Enterprises Ltd)**	**5 (Bliss Gvs Pharma Ltd)**	**6 (C. Mehta & Co. Ltd)**	**7 (Royter Investments Ltd)**	**8 (Surgilinks Ltd)**
Valid Tax Compliance Certificate	Yes 16/003622/2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Yes	Yes-18/014368/2011	N/A-International bidder	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Yes
Certificate of Incorporation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
VAT Certificate	Yes	Yes	Yes	Yes	N/A-International bidder	Yes	Yes	Yes
PIN Certificate	Yes	Yes	Yes	Yes	N/A-International bidder	Yes	Yes	Yes

Business Questionnaire duly filled	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Declaration of undertaking signed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Original Bid Bond	Yes-First Assurance	Yes-The Monarch Insurance	Yes-GA Insurance	Yes-APA Insurance	Yes-AMACO	Yes-Occidental insurance	Yes-Equity Bank	Yes-KCB
Bid Bond 2% of Bid value	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bid Bond Valid for 120 days	Yes-18th March 2012	Yes-17th March 2012	Yes-5th May 2012	Yes-150 days	Yes-150 days	Yes	Yes	Yes-20th Feb. 2012
Tender form duly completed stamped and signed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Official Receipt	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Verdict	**PASS**	**FAIL**	**PASS**	**PASS**	**PASS**	**FAIL**	**FAIL**	**PASS**

Bidder	9 (Ecolat Medical Supplies)	10 (Harleys Ltd)	11 (PAL International)	12 (A One Healthcare Ltd)	13 (York Investments E.A. Ltd)	14 (Beijing Holley Cotec Ltd)	15 (Hartwood Enterprises)	16 (Famy Care International)
Valid Tax Compliance Certificate	Yes 06/011324/2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	N/A-International bidder	Invalid Tax Compliance Certificate as per letter from KRA dated 10th November 2011	N/A-International bidder
Certificate of Incorporation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
VAT Certificate	Yes	Yes	Yes	Yes	Yes	N/A-International bidder	Not provided	N/A-International bidder
PIN Certificate	Yes	Yes	Yes	Yes	Yes	N/A-International bidder	Not provided	N/A-International bidder
Business Questionnaire duly filled	Yes	Yes	Yes	Yes		Yes	Yes	Yes

Declaration of undertaking signed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Original Bid Bond	Yes-Equity Bank	Yes-GA Insurance	Yes-AMACO	Yes-Occidental Insurance	Yes-APA Insurance	Yes-Guang Dong Development Bank	Yes-African Banking Corporation	Yes-Standard Chartered
Bid Bond 2% of Bid value	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bid Bond Valid for 120 days	Yes-20th April 2012	Yes-17th February 2012	Yes-150 days	Yes-150 days	Yes-18th April 2012	Yes-6th March 2012	Yes-18th feb 2012	Yes-29th Feb 2012
Tender form duly completed stamped and signed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Official Receipt	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Verdict	**PASS**	**FAIL**	**FAIL**	**FAIL**	**FAIL**	**PASS**	**FAIL**	**PASS**

Recommendations

i. Bidders No. 1, 3, 4, 5, 8, 9, 14 and 16 met all requirements and proceeded to the next stage of evaluation. Clarification was sought for bidder No. 8 (Surgilinks Ltd) to provide a certified tax compliance certificate and this requirement was met as per letter dated 11th November 2011.

ii. For Bidders No. 2, 6, 7, 10, 11, 12, 13 and 15- The Technical evaluation committee was unable to authenticate their Tax Compliance Certificates using the KRA online facility. A letter was therefore written to KRA requesting them to confirm the authenticity of the Tax Compliance Certificates for these bidders. KRA vide their letter dated 10th November 2011 confirmed that the certificates could not have been issued from their office and advised KEMSA to regard them as not genuine. These bidders were therefore disqualified from further evaluation.

Findings - Technical Examination - Documents

Eight (8) bidders were subjected to a Technical Evaluation. The findings were as tabulated hereunder:

	Bidder No.					
Bidder No.	**1 (Angelica Medical Supplies)**			**3 (Biodeal Laboratories Ltd)**		
Tenderer has a valid Wholesale dealer's licence/Good Distribution Practice (GDP) /Freesale certificate or equivalent from recognised regulatory Authority	Yes	WDL No. 14388	Exp Date: 31st Dec 2011	Yes	WDL No- 14298	Exp Date: 31st Dec 2011
Manufacturing licence from recognised regulatory Authority	N/A	Agent not Manufacturer		Yes	ML No- 1981	Exp Date: 31st Dec 2011
Tenderer has a valid GMP certificate from recognised regulatory Authority	N/A	Agent not Manufacturer		Yes	GMP No- PPB/GMP/L/2011/05	Exp Date: 31st January 2012
Certificate of Superintendent/Production Pharmacist Provided	Yes	Name: Dr. LarryKariuki Kamamia	Reg No. 1487	Yes	Name - Dr. S. Chandrasekhar	Reg No. 1280
marketed specific goods for at least two (2) years and similar goods for at	Yes	Provided		Yes	Provided	
Manufacturing site for the **drugs** is dedicated to the manufacture of hormonal products only	Yes	Statement from Pfizer submitted		Yes	Evidence provided as per GMP certificate	
		Manufacturer/ Agent	**GMP Certificate Provided ?**		**Manufacturer/ Agent**	**GMP Certificate Provided ?**
Manufacturer's Authorization Given	Yes	Pfizer global supply-depo vera	No. BE/2011/017 Exp 16th June 2014	Yes	West-coast Pharmaceuticals-EC	GMP No. 1009405 Exp 6th April 2012
	Yes	All-Pro Corporation-gloves n spirit swabs	No. HD60023686 0001 Exp 25.12.2013, No. HD60023683 0001 Exp 25.12.2013	Yes	Indus Medicare Ltd-condoms	ISO 13485: 2003 Exp 13th Oct 2013
	Yes	Snaa Industries	No. MI ISO 9001:2008 Cert No. 06106 Exp 29th Sept 2012			
	Yes	Becton Dickinson (BD)-Syringes	No. AENOR GA-1998/0105 Exp 15.12.2012			
Comment	Bidder met all regulatory documentation requirements			Bidder met all regulatory documentation requirements		

	Bidder No.					
Bidder No.	**4 (Nairobi Enterprises Ltd)**			**5 (Bliss Gvs Pharma Ltd)**		
Tenderer has a valid Wholesale dealer's licence/Good Distribution Practice (GDP) /Freesale certificate or equivalent from recognised regulatory Authority	N/A	Bidding for non Pharmaceutical items		N/A	Bidding for non Pharmaceutical items	
Manufacturing licence from recognised regulatory Authority	N/A	Agent not Manufacturer		N/A	Agent not Manufacturer	
Tenderer has a valid GMP certificate from recognised regulatory Authority	N/A	Agent not Manufacturer		N/A	Agent not Manufacturer	
Certificate of Superintendent/Production Pharmacist Provided	N/A	Bidding for a non Pharmaceutical item		N/A	Bidding for a non Pharmaceutical item	
marketed specific goods for at least two (2) years and similar goods for at	Yes	Provided		N/A	Not applicable	
Manufacturing site for the **drugs** is dedicated to the manufacture of hormonal products only	N/A	Not applicable-Bidding for non Pharmaceutical items		N/A	Not applicable-Bidding for non Pharmaceutical items	
		Manufacturer/ Agent	**GMP Certificate Provided ?**		**Manufacturer/ Agent**	**GMP Certificate Provided ?**
Manufacturer's Authorization Given	Yes	Henan Xibei Latex Co. Ltd-condoms	ISO 9001:2008 Exp 7th June 2013	Yes	Mercator Healthcare Ltd-condoms	DNV No. 11376-2007-CE-NOR Exp 14/03/2013, SABS No. 7128/10716 Exp 20/08/2011
	Yes	Ajara International-IUCD	No. 04-A-10-QMS-0020 Exp 30th Jan 2012	Yes	Tianjin Condombao Medical Tech Co. Ltd	No. CNAB No. 047121s10161RIM Exp 9th August 2014
	No	Tianjin Condombao Medical Tech Co. Ltd	Not provided			
COMMENT	Bidder did not meet all regulatory documentation requirements			Bidder met all regulatory documentation requirements		

	Bidder No.					
Bidder No.	**8 (Surgilinks Ltd)**			**9 (Ecolat Medical Supplies)**		
Tenderer has a valid Wholesale dealer's licence/Good Distribution Practice (GDP) /Freesale certificate or equivalent from recognised regulatory Authority	N/A	WDL No. 14178	Exp 31st December 2012	N/A	Bidding for a non Pharmaceutical item	
Manufacturing licence from recognised regulatory Authority	N/A	Agent not Manufacturer		N/A	Agent not Manufacturer	
Tenderer has a valid GMP certificate from recognised regulatory Authority	N/A	Agent not Manufacturer		N/A	Agent not Manufacturer	
Certificate of Superintendent/Production Pharmacist Provided	N/A	Dr. Winnie Wanjiru Munene	Reg No. 2289	N/A	Bidding for a non Pharmaceutical item	
marketed specific goods for at least two (2) years and similar	N/A	Not applicable		N/A	Not applicable	
Manufacturing site for the **drugs** is dedicated to the manufacture of hormonal products only	Yes			N/A	Not applicable-Bidding for non Pharmaceutical items	
Manufacturer's Authorization Given		**Manufacturer/ Agent**	**GMP Certificate Provided ?**		**Manufacturer/ Agent**	**GMP Certificate Provided ?**
	Yes	Unicure Remedies Pvt. Ltd-EC	No. PPB/GMP/F/2010/41 Exp 31/07/2013	Yes	Thai Nippon Rubber Industry Co. Ltd-condoms	SGS ISO 13485:2003 Exp 11/02/2014
				Yes	Wrangler Instruments-IUCD insertion kits	ISO 13485:2003 Exp 25/11/2013
	Bidder met all regulatory documentation requirements			Bidder met all regulatory documentation requirements		

	Bidder No.					
Bidder No.	**14 (Beijing Holley Cotec Ltd)**			**16 (Famy Care International)**		
Tenderer has a valid Wholesale dealer's licence/Good Distribution Practice (GDP) /Freesale certificate or equivalent from recognised regulatory Authority	N/A	Bidding for a non Pharmaceutical item		N/A	International bidder	
Manufacturing licence from recognised regulatory Authority	N/A	Agent not Manufacturer		Yes	ML No. G/1476 and G/1072	Exp: 31st December 2011
Tenderer has a valid GMP certificate from recognised regulatory Authority	N/A	Agent not Manufacturer		Yes	GMP No.PPB/GMP/F/2011/036	Exp: 31st June 2014
Certificate of Superintendent/Producti on Pharmacist Provided	N/A	Bidding for a non Pharmaceutical item		N/A	International bidder	
marketed specific goods for at least two (2) years and similar goods for at	N/A	Not applicable		Yes	Provided	
Manufacturing site for the **drugs** is dedicated to the manufacture of hormonal products only	N/A	Not applicable		Yes	Evidence shown as detailed in their manufacturing Licence given by the regulatory authority and GMP from PPB	
		Manufacturer/ Agent	**GMP Certificate Provided ?**		**Manufacturer/ Agent**	**GMP Certificate Provided ?**
Manufacturer's Authorization Given	Yes	Hebei Angel Latex Co. Ltd-condoms	ISO 9001:2008 Exp 19/08/2013	Yes	PT Harsen Laboratories-DMPA	No. PPB/GMP/F/2010/27 Exp 30th April 2013
				Yes	Time technoplast-syringes	ISO 13485:2003 Exp 18th July 2013
				Yes	P.T Latexindo Tobaperkasa-gloves	ISO 13485:2003 Exp 05/02/2012
				Yes	Mak Medicals Ltd-swabs	ISO 9001:2008 Exp 8th March 2014
Comments	Bidder met all regulatory documentation requirements			Bidder met all regulatory documentation requirements		

Recommendations

1. Bidders No's 1 (Angelica Medical Supplies), 3 (Biodeal Laboratories Ltd), 5 (Bliss Gvs Pharma Ltd), 8 (Surgilinks Ltd), 9 (Ecolat Medical Supplies), 14 (Beijing Holley Cotec Ltd) and 16 (Famy Care Ltd) met all the regulatory

documentary requirements, and thus qualified to proceed to the next stage of evaluation.

2. Bidder No. 4 (Nairobi Enterprises Ltd) failed to provide a Manufacturer's Authorization letter and Certificate of quality for Tianjin Condombao Medical Tech Co. Ltd therefore item No. 5 (Female Condom, Pieces) was disqualified from further evaluation.

Product Evaluation

Item No. 1: Depot Medroxyprogesterone Acetate 150mg/ml -Kit (100 vial)

Two (2) samples from bidders No's 1 (Angelica Medical Supplies Ltd) and 16 (Famy Care Ltd) were received for evaluation as summarized below:

Bidder No. 1

Angelica Medical Supplies Ltd

Line No	Item Description		Manufacturer	Brand	Country of Origin	% Technical Score	Registration Status	Comment
1	Depot Medroxyprogesterone aceate 150mg/ml -Kit (100 vial)	100 vial	Pharmacia N.V./S.A., Puurs	Depo-Provera	Belgium	100.00%	Registered	Acceptable
2	Spirit Swabs	100s	All Pro Corporation	spirit swabs	China	98.00%	N/A	Acceptable
3	Latex examination (non-sterile medium) gloves, pre-powdered,	100s	All Pro Corporation	All pro	China	100.00%	N/A	Acceptable
4	2 ml sterile re-use prevention syringes with 100 needles of G21 length 1.5inch, 2 piece	100s	BD Solomed	BD	Spain	93.85%	N/A	Bidder attached a statement indicating they will comply to supply size 1.5

No. of Items in the Tender	4
No. of samples submitted	4
No. of samples acceptable	4
% of samples acceptable	100.00%

Recommendation of the Technical Committee

i. The Kit from bidder No. 1 (Angelica Medical Supplies Ltd) met all the requirements for GMP, product registration and had at least 75% of the products in the kit scoring 95% total weighted score and is therefore acceptable.

ii. Alcohol Swabs- bidder should be compelled to indicate manufacturer name on the individual pack in case of award.

Bidder No. 16

Famy Care Ltd

Line No	Item Description		Manufacturer	Brand	Country of Origin	% Technical Score	Registration Status	Comment
1	Depot Medroxyprogesterone aceate 150mg/ml -Kit (100 vial)	100 vial	Harsen	Depo progestin	Indonesia	100.00%	Registered	Acceptable
2	Spirit Swabs	100s	Mak Medicals Ltd	spirit swabs	India	100.00%	N/A	Acceptable
3	Latex examination (non-sterile medium) gloves, pre-powdered,	100s	P.T. Latexindo Tobaperkasa	Skin Tex	Indonesia	100.00%	N/A	Acceptable
4	2 ml sterile re-use prevention syringes with 100 needles of G21 length 1.5inch, 2 piece	100s	Time Technoplast	Auto break	Kenya	100.00%	N/A	Acceptable

No. of Items in the Tender	4
No. of samples submitted	4
No. of Samples acceptable	4
% of samples acceptable	100.00%

Recommendation of the Technical Committee

i. The Kit from bidder No. 16 (Famy Care Ltd) met all the requirements for GMP, product registration and had at least 75% of the products in the kit scoring 95% total weighted score and is therefore acceptable.

FINANCIAL EVALUATION

Item No. 1: Depot Medroxyprogesterone Acetate 150mg/ml -Kit (100 vial)

Financial evaluation for the two responsive bidders is summarized in the following table:

Bidder No.	Bidder Name	Qty	Unit Price (bidders currency)	Exchange Rate	Unit price (Ksh)	Total Cost (Bidder's Currency)	Total Cost (Ksh)	Delivery Schedule
1	Angelica Medical Supplies Ltd	63,706	USD 95.50	99.3417	9487.13	USD 6,083,923.00	604,387,253.49	8-12 Weeks
16	Famy Care Ltd	63,706	USD 96.99	99.3417	9635.15	USD 6,178,844.94	613,816,960.38	12 Weeks and as per KEMSA Requirement

Recommendation:

The Committee recommends the award to Angelica Medical Supplies Ltd at a unit price of USD 95.50 and at a total cost of USD 6,083,923.00 being the lowest responsive evaluated bidder.

TENDER COMMITTEE DECISION

The Kenya Medical Supplies Agency Tender Committee in its meeting held on 15th December 2011, discussed Tender No. KEMSA/OIT/60-2011-2013 for Procurement of Family Planning Commodities and concurred with the Technical Committee's recommendations and awarded the item as follows:-

Item No./ Description	Supplier	Qty	Unit Price (USD)	Total Cost (USD)	Delivery	Justification
Item No. 1- Depot Medroxyprogesterone acetate 150mg/ml - Kit (100 vial)	Angelica Medical Supplies Ltd	63,706	95.50	6,083.923.00	8-12 weeks	Lowest evaluated responsive bidder

The Tender Committee's decision was communicated to the tenderers via letters dated 19th December, 2011.

THE REVIEW

The Applicant lodged this Request for Review on 28th December, 2011 against the decision of the Tender Committee of Kenya Medical Supplies Agency dated 19th December, 2011 in the matter of Tender No. KEMSA/OIT60/2011-2013 for the Supply of Family Planning Commodities. The Applicant was represented by Mr. Muriuki Mugambi, Advocate while the Procuring Entity was represented by Mr. Fred Wanyonyi, Director, Legal Services. The Successful Bidder, Angelica Medical Supplies Limited was represented by Mr. Julius Ogamba, Advocate. Other interested parties present included Harleys Ltd represented by Mr. Vinoo Guptan, Sales & Marketing Director, Nairobi Enterprises Limited represented by Ms. Constance A. Oyugi, PAL International represented by Mr. Antony Mugodo and Hartwood Limited represented by Mr. David Mathenge.

The Applicant requests the Board for the following orders:-

(a) That, the Applicant be and is hereby declared the successful bidder

(b) That, Tender No. KEMSA/OIT60/2011-2013 for the Supply of Injectable Contraceptives be and is hereby awarded to the Applicant, Famy Care Limited.

(c) Such other and or further orders as may be necessary to give effect to the above orders do issue.

In its Request for Review, the Applicant raised four grounds of review which the Board deals with as follows:-

Grounds 1, 2, 3 and 4: – Breach of Sections 31, 34, 59(3), 64(1), 66(2), 67(1) and 68(1) of the Act and Clauses 6.2 of the Tender Document.

These grounds have been consolidated as they raise similar issues on the responsiveness of the successful bid to the Technical Specifications for the supply of product (Depot Medroxyprogesterone Acetate 150mg/ml) as required by the Procuring Entity.

The Applicant submitted that it was a manufacturer and had participated in the tender with a product fulfilling the entire technical criteria sought by the Procuring Entity as per the tender documents. Further, it submitted that its product conformed in all aspects to the Pharmacy and Poisons Board requirements and hence believed that it was the only technically responsive bidder.

The Applicant submitted that it was aware that the product offered to the local market by its competitor namely Pfizer whose local agent M/S Angelica Medical Supplies was the Successful Bidder, does not conform to the tender requirements of Clause 6.2 of the Tender Document.
It further submitted that the product submitted by the Successful Bidder did not conform to the World Health Organization (WHO) drug stability testing requirement for tropical regions and particularly with regard to temperature and relative humidity.

The Applicant stated that it was aware that one of the bidders, M/s PAL International Limited, relied on a manufacturer who has, in previous

proceedings before the Board and in a tender in which the Applicant participated and won, had been disqualified by reason that the products did not meet Good Manufacturing Practice (GMP) requirements and therefore failed to meet the Pharmacy and Poisons Board (PPB) requirements.

The Applicant argued that the Procuring Entity's decision to award the above tender to any bidder other than itself was a direct breach of the letter and spirit of the Public Procurement and Disposal Act, 2005 and in particular by awarding a tender to a non-responsive bidder whose product poses a significant risk to the extent that the product fails to meet the World Health Organization's recommendations for tropical formulations.

In support of its allegations, the Applicant submitted that it had purchased, from the local market, samples of the product brand supplied by the Successful Bidder and manufactured by Pfizer namely Depo Provera. It stated that, upon purchase, it found out from the label that the product should not be stored above 25° C and had a shelf life of 3 years. It referred the Board to Page 208 of its Request for Review where it had annexed copies of the packaging label of the said product. It therefore contended that the product did not meet the requirements of Clause 6.2 and Annexure "C" Clause 19 of the Tender Document and that on this account, the Procuring Entity ought to have disqualified the Successful Bidder's bid. Further, it stated that the requirements relating to standards of quality assurance formed an integral part of the tender and accordingly, failure to adhere to the said qualifications by the Procuring Entity was a breach of the Sections 31 and 34 of the Act.

With regard to product registration, the Applicant submitted that it had

written to the Pharmacy and Poisons Board vide its letter Ref. F10/002/L/09 dated 19th January 2012 seeking to know if the product by Pfizer as offered by the Successful Bidder had a current valid registration and also the products' storage conditions with regards to temperature and relative humidity. To this end, it submitted that it had received a reply from the Pharmacy and Poisons Board Ref. PPB/LEG/VO11/(042)/012 indicating that the product was validly registered for 5 years and that the registration was granted on the basis of the following storage conditions:-

(a) Temperature 25 ± 2°C

(b) Humidity 65 ± 5%.

Finally, with regard to the quality of the product by Pfizer, it submitted that the letter from Pharmacy and Poisons Board also indicated that the product had a shelf life of 3 years while the Procuring Entity required a product with a shelf life of 5 years.

In conclusion, it submitted that the technical evaluation was flawed and that the Procuring Entity's decision to reject it's tender, having been the only technically responsive bidder was in breach of the provisions of Sections 31, 34, 59, 64, 66, 67, 68 and 71 of the Act. It also argued that, in light of the concerns raised above, the failure by the Procuring Entity to notify the Applicant of an award of the contract constitutes an express breach of section 67(1). It urged the Board to allow the application and award costs to it.

In its response, the Procuring Entity submitted that, the Application, as filed was frivolous and urged the Board to invoke its powers under Section 93 (2)

(d) and dismiss the application.

The Procuring Entity denied the Applicant's claim that it was the only technically responsive bidder. It submitted that there were two responsive bidders at the technical evaluation stage for the subject product (Depot Medroxyprogesterone Acetate 150mg/ml) - namely the Applicant and the Successful Bidder. It further submitted that when the two bids were financially evaluated, the Applicant was found to be non-competitive and hence disqualified. It submitted that the technical evaluation team was constituted by the Chief Executive Officer of the Procuring Entity in line with the law and comprised of competent persons.

With regard to the Successful Bidder (Angelica Medical Supplies Ltd), the Procuring Entity submitted that the Successful Bidder was the appointed agent for the manufacturer of the original brand (Pfizer International Corporation) which had been in the Kenyan market for over thirty (30) years. It further submitted that the Government of Kenya through the Procuring Entity procures only a quarter (1/4) of the country's requirement of this product while the other bulk of the requirement has been met by Development Partners that have been procuring the product through UNFPA and distributing to the Government of Kenya through the Procuring Entity.

It submitted that the product had been used over the years in the country without any quality issues.

With regard to the quality of the product, the Procuring Entity stated that the quality, stability, efficacy and safety of this product had never been in doubt. It stated that the product was registered by the Pharmacy and Poisons Board

(PPB) which has the mandate to establish the right quality of such products in Kenya. It further submitted that one of the requirements before registration is that the Pharmacy and Poisons Board confirms the stability of the product within the temperature ranges of Kenya. It argued that, the said product brand, having been registered by Pharmacy and Poisons Board was of high quality and met the stability requirements in the country and that if the brand had quality issues, the Pharmacy and Poisons Board would have withdrawn its marketing authorization in the country. The Procuring Entity submitted that the Successful Bidder had in the past participated in tenders for the same product and lost to the Applicant on account of price and not quality.

The Procuring Entity submitted that the Applicant's brand is a generic version of the original brand (Depo Provera) and had only been in the Kenyan market since the year 2007.

With regard to PAL International, the Procuring Entity submitted that, PAL International had not supplied it with similar product in the past. It pointed out that the Applicant's claim that PAL International Ltd was a responsive bidder in this tender is erroneous in that its bid was disqualified at the preliminary evaluation stage for being non-responsive and hence did not proceed for technical evaluation stage.

Turning to the quality issues raised by the Applicant about the product offered by the Successful Bidder, the Procuring Entity submitted that the product whose label was presented before the Board by the Applicant was not the same one presented to it by the Successful Bidder for evaluation. In

support of its submissions, it tabled before the Board the sample of the product submitted by the Successful Bidder for evaluation. It referred the Board to the product leaflet contained therein which stated as hereunder with regard to storage;

"Store at controlled room temperature 15 °C to 30 °C (59 ° to 86 ° F)"

Further the same sample indicated the product shelf life to be five years.

With regard to the letter from the PPB Ref. PPB/LEG/VOII/(042)/012 dated 20th January 2012 presented by the Applicant, the Procuring Entity submitted that the said letter was not properly signed in that it had been signed by the Legal Officer and not the Registrar in accordance with Section 9 of Pharmacy and Poisons Board Rules.

In conclusion, the Procuring Entity submitted that it had not breached any provisions of the Act and its Regulations during the tendering process and urged the Board to dismiss the application with costs.

On its part, the Successful Bidder M/S Angelica Medical Supplies Limited submitted that the Applicant had based its Request for Review on issues which were not factual and that the Applicant lacked evidence on the allegations it was making.

It further submitted that the Applicant was not a manufacturer contrary to the information given by the Applicant. It added that there was no illegality with regard to the evaluation since the evaluations were carried out by the same team which had awarded the Applicant item Nos. 2 and 3 of the same tender.

It submitted that the letter produced by the Applicant from the Pharmacy and

Poisons Board was not consistent with Pharmacy and Poisons Board rules and that the letter authored by the Legal Officer could not meet the requirements of Section 35(4) of the Evidence Act. To this end, it stated that the said letter, for it to be valid, could only come from the Registrar's office and not any other office.

In conclusion, it submitted that the application was speculative, anticipatory and should be dismissed with costs.

In support of the Successful Bidder, Pfizer International Corporation (the manufacturer of the product offered by the Successful Bidder) through their Regional Director for Central and Eastern Africa (Mr. Seroney) submitted that the product in question was initially manufactured by a company called Upjohn which was acquired by Pharmacia which in turn merged with Pfizer. He explained that the reason for having a product in the market lingering the identity of the previous product is that; globally, it takes a lengthy period to change the regulatory process across the board in order to alter the identity of a product.

He further submitted that the packaging of the product is differentiated according to a customer's special characteristics, for example the Procuring Entity in this case being a bulk buyer was offered the product in its bulk package as opposed to the single dose package which is available in the open market. He further submitted that their product is also differentiated by manufacturing area with the product manufactured in USA, which is meant for the open market, packaged as 1 unit per packet and having a shelf life of 36 months whereas the one manufactured in Belgium is packaged as 25 units

per packet and having a shelf life of 60 months. He submitted that the sample product presented to the Procuring Entity and to the Board is manufactured in Belgium.

With regard to the registration of the product Depo Provera from Belgium, Mr. Seroney urged the Board to independently confirm from the Pharmacy and Poisons Board. He argued that if the product is not registered, then the World Health Organization, USAID, UNFPA and Pfizer would have been committing an illegality over that breach as the product in question has continuously and on a regular basis been supplied into Kenya. He further submitted that the Depo Provera with a shelf life of 36 months was introduced by Pfizer in the market 3 years ago as a stop gap measure to address a global shortage of the product.

An interested Party, M/s PAL International Limited submitted that the statement by the Applicant that its production plant did not meet Good Manufacturing Practice standards was not true.

Another Interested Party, M/s Hartwood Enterprises, through Mr. David Mathenge urged the Board to look at the qualifications of the subject product when deciding on the issue of the storage conditions.

The Board has carefully considered the submissions of the parties and the documents presented before it.

The Board notes that the tender was for supply of 7 items namely:

1. Injectable contraceptive kits containing 150mg Dimedroxyprogesterone Acetate

2. Progesterone - only Pills, (POP) 0.03mg
3. Emergency Contraceptive Pills (EC) 0.75mg
4. Male Condoms
5. Female Condoms
6. Cycle Beads (Standard Days Method) and
7. IUCD Insertion Kits.

The Board however notes that the Applicant had only tendered for item No's 1, 2 and 3 above though the Request for Review was for the whole tender.

The Board at this juncture observes that all the submission by the parties is in regard to item No 1 while no issues were raised in regard to the other six items two of which the Board notes were awarded to the Applicant. Accordingly, the Board holds that this Request for Review only relates to item No. 1, namely Supply of injectable contraceptive kits containing 150mg Dimedroxyprogesterone Acetate.

At the onset, the Board notes that the only bone of contention, which require determination by the Board is whether the product proposed by the Successful Bidder met the requirements of the Tender Document and in particular Clause 6.2 and Annexure "C" Clause 19 of the Tender Document.

The Board notes the provisions of Clause 6.2, Annexure "C" Clause 19 and Clauses 5.1 and 7.1 under Section V of the Tender Document which state as follows:-

Clause 6.2:-

"Only tropical formulations and packages should be supplied. All products supplied should remain stable within the product's shelf life. The procuring Entity reserves the right to reject medical commodities that are not suitable for the tropical climate. The product should be stable at control room temperature up to 30 ° C throughout the shelf life. This needs to be substantiated with real time stability data."

Annexure "C" Clause 19:-

"Product Specifications:

All specifications stated on the tender sent to KEMSA and confirmed on the purchase order must be adhered to, i.e. stated strength, pack size, manufacturer, labeling and markings, etc.

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SPECIFICATIONS FOR CONTRACEPTIVES

Item No.	*Item Description*	*Unit Pack*	*Specifications*
1	*Injectable Contraceptives consisting of : Progestin only Injectable containing 150mg Dimedroxyprogesterone acetate*	*Kit*	*100 vials DMPA with 100 pieces of 2 ml sterile re-use prevention syringes with 100 needles of G21 length 1.5inch, 100 Spirit swabs, 100 pairs Latex examination gloves (non-sterile, medium size, pre-powdered), and 100 pieces of client Leaflets in both English and Kiswahili. Shelf-life of 5 years (>80% a time of delivery)"*

Clause 5.1:-

"All products must:

(a)Be manufactured in conformity with the latest edition of British, International United States, French or European Pharmacopoeia. If the product is not included in the specified Compendia, the bidder

upon being awarded the order must provide the reference standards and testing protocols to allow for quality control

(b) Be manufactured in accordance with Good Manufacturing Practice (GMP)

(c) Be registered with the Kenya Pharmacy and Poisons Board, and the registration status must be current.

(d) ….

(e) ….

(f) …"

Clause 7.1:-

"Bidders must provide the following documentary evidence of the tenderers qualifications to perform the Contract if its Bid is accepted;

(i) That in the case of a bidder offering to supply Medical Commodities under the contract that the tenderer manufactures or otherwise produces (using ingredients supplied by primary manufactures) that the bidder:

(a) Is incorporated in the country of manufacture of the medical commodities

(b) Has been licensed by the regulatory authority in the country of manufacture to supply the medical commodities

(c) Has received satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in international commerce. Where the Kenyan Regulatory Authority has inspected the site, their findings shall supersede any other findings by other regulatory authorities

(d)For all non Pharmaceuticals, bidders must submit valid certificates of quality issued by recognized authorities.

(e) That the manufacturing site for the drugs is dedicated to the manufacture of hormonal products only. Submit a copy of the recent inspection report from a recognized regulatory authority. Where the Kenyan Regulatory Authority has inspected the site, their findings shall supersede any other findings by other regulatory authorities.

(f) ... ...

(g) ... ...

(ii) That in the case of a tenderer offering to supply medical commodities under the contract that the tenderer does not manufacture or otherwise produce:

(a) That the tenderer has been duly authorized by the manufacturer of the medical commodities that meet the criteria under (i) above to supply the medical commodities in Kenya, and

(b) That the tenderer has been duly authorized by the manufacturer of medical commodities that meets the criteria under (i) (c) above

(c) ... ...

(d) ... ..."

Before the Board makes a determination on the subject issue, it is important that it summarizes the following factual information:-

1. That the Applicant wrote to the Pharmacy and Poisons Board through its Lawyers vide letter Ref. F10/002/L/09 dated 19th January 2012. This letter

was not part of the bundle of documents that formed the Request for Review but was presented to the Board during the hearing.

2. That the above stated letter asked the Pharmacy and Poisons Board to confirm if Depo Provera was validly registered and if so, the products storage conditions as regards temperature and relative humidity.
3. That the Pharmacy and Poisons Board responded promptly by its letter Ref. PPB/LEG/VOL.II / (042)/012 dated 20th January 2012 signed for registrar by one Dr. Joseph Yano in the capacity of Legal Officer.
4. That the letter referred to in paragraph 3 above stated the following with regard to storage conditions among other things:-
    - That the Product is validly registered for a period of 5 years under Registration No. 0782
    - That the registration of the product was granted on the basis of the following storage conditions:
        (1) Temperature 25 ± 2°C
        (2) Humidity 65 ± 5%.
5. That the Procuring Entity had earlier on received a letter from Pharmacy and Poisons Board, Ref. PPB/DRGREG/VOL.1/010/(012) dated 15th November 2011, whose subject matter was clarification on product registration. The information was meant to assist the Procuring Entity during the evaluation of the subject tender.
6. That the letter referred to in paragraph 5 above also confirmed that, the Product Depo-Provera registration 0782 was, among other products validly registered by the PPB and that the product ex- USA had a shelf life of three years while the same from Belgium has a shelf life of 5 years.

7. (a)That during the hearing, the Procuring Entity presented to the Board the product sample which was used for evaluation. The product label stated that the product could be stored at controlled temperature of between 15 and 30 degrees Celcius and had a shelf life of 5 years.

   (b)That the Applicant also presented a sample product to the Board which indicated storage condition of up to 25 degrees Celcius and a shelf life of 3 years.

8. That there was a difference in the packaging of the two sample products presented to the Board by the Procuring Entity and the Applicant respectively.

The Board observes that during the hearing, the Applicant did not dispute the argument and presentation by the Procuring Entity that the product used for evaluation was different from the one the Applicant had bought from the local market.

The Board notes that the product offered by the Successful Bidder is registered by the Pharmacy and Poisons Board under Certificate of Registration No. 0782. The Board further notes that the product is prequalified under the World Health Organization (WHO) Prequalification of Medicines Programme (a copy of WHO letter dated 20th October 2010 communicating the same was provided as part of the bid documents).

With regard to storage conditions, the Board notes that the stability report submitted by the Successful Bidder was supported by two different sets of stability data, with one set indicating that the product is stable up to testing periods when stored at 25° C - 60% RH and the other indicating that the product is stable up to testing periods when stored at 30°C and 65% RH.

The Board finds that the requirements for product stability and shelf life as set out in the Tender Document were:-

Temperatures up to 30 degrees and a shelf life of 5 years.

In this regard, the Board finds that the Successful Bidder, based on the sample provided by the Procuring Entity which is made in Belgium, met these requirements.

The Board further finds that the Applicant has not provided any evidence to prove that the Depo Provera and Depot Medroxyprogesterone acetate 150mg/ml is not one and the same product. In view of this, the Board finds that the allegation made by the Applicant with regard to the quality and stability of the product is unsustainable.

The Board finds that, in the instant case, the local regulator (Pharmacy and Poisons Board) which has the duty and capacity to ensure that all the pharmaceutical products to be supplied in the country are suitable for the local conditions and are not harmful to the consumers/users in any way issued two contradictory letters Ref. PPB/DRGREG/VOL.1/010/(012) dated 15th November 2011 and Ref. PPB/LEG/VOL.II /(042)/012 dated 20th January 2012 to the Procuring Entity and the Applicant respectively on the subject product. The Board notes that under Rule 9 of the Pharmacy and Poisons Board Rules, confirmation as to whether a drug is registered or not should be confirmed by the Registrar and it is not clear under what circumstances the Legal Officer wrote a letter dated 20th January 2012.

With regard to PAL International, the Board finds that this bidder was disqualified at the preliminary stage of evaluation after Kenya Revenue

Authority confirmed that the Tax Compliance Certificate presented by the bidder was not genuine.

Taking all the above matters into consideration, the Board finds that the Procuring Entity did not breach any of the cited Sections of the Act. Consequently, all the grounds of the appeal fail.

Statement on Loss and Damage Suffered

This is not a ground of review but the Applicant's statement of loss.

The Board has held severally that tendering costs are commercial business risks borne by business people and therefore each party bears its cost.

Taking all the above matters into consideration, the Request for Review fails and is hereby dismissed. The Board orders, pursuant to Section 98(b) of the Act that the procurement process may proceed. Further, in view of the two contradictory letters from the Pharmacy and Poisons Board, the Procuring Entity shall ensure that the drug which was item No.1 of the tender is duly checked, cleared and certified for public use by the Pharmacy and Poisons Board and the National Quality Control Laboratory in accordance with clause 7.1 of the tender document.

There are no orders as to costs.

Dated at Nairobi on this 27th Day of January 2012.

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CHAIRMAN
PPARB

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SECRETARY
PPARB