Decision No. 20/15

INDEPENDENT REVIEW PANEL

In the matter of:

Ducray Lenoir Ltd

(Applicant)

v/s

Ministry of Health & Quality of Life

(Respondent)

(Cause Nos. 12/15/IRP)

Decision

A. History of the case

On the 03rd December 2014, the Ministry of Health & Quality of Life issued a tender through Open National Bidding for the Procurement of Glucosemeters and Test strips for determination of glucose in blood (Procurement Reference No: ONBIMHPQIMDIS/2014/Q35).

The project consists of the supply of the following:

300 sets of Glucosemcters with the following specifications:

(a) Able to perform around 100 tests consistently (and at a go) and user friendly.

(b) Compatible for use in all units of the health institutions, including neonatal units.

(c) Reliable (evaluated and cleared by FDA-USA or MHRA-UK or ISO 15197 certified: relevant reports or certificates to be submitted).

(d) Have a warranty of at least 3 years.

(e) Capillary filled test strip system.

(f) Automatic calibration or using calibrator chip.

(g) Sample type: capillary, venous and neonatal.

(h) Provision for alternative site testing

(i) Result type: Plasma calibrated and reported in mmol/L

j) Sample volume: less than 5 µl

(k) Measurement time: up to 10 secs

(I) Measurement range: 2 to 27 mmol/L

(m) Haematocrit range 20-65%

(n) Operating temperature 15-40DC and humidity up to 85%

(0) Interferences and limitations of method must be provided in user manual/Kit inserts

(p) System must provide Quality control samples

(q) The glucosemeter should be provided in a case or bag and comprise one pricking device, ten lancets and user manual/guide leaflet and package inserts.

(r) The make of the glucosemeters and test strips proposed by the bidders should be available for the sale use in the health services of the Ministry of Health and Quality of Life.

(s) The make, manufacturer's name and country of origin should be printed / embossed on the primary packaging material by the manufacturer.

And 121,500 boxes of 50 test strips foiled or un-foiled or 60,750 boxes of 100 test strips individually foiled of Test strips for determination of glucose in blood to be compatible with above item with the following specifications:

(a) Storage temperature: I5-300C and humidity up to 85%.

(b) Test strips must have a shelf life of at least 12 months at time of delivery of each consignment.

(c) The make, manufacturer's name, country of origin, manufacturing date and expiry date should be printed I embossed on the primary packaging material by the manufacturer.

Invitation of bids was through Open Advertised Bidding (National) in "Le Matinal" and "Le Socialiste" newspapers on 05 December 2014, 08 December 2014 and 10 December 2014, and posting on PPO's website at publicprocurement.gov.mu on 03 December 2014 with closing date being 21 January 2015 up to 13.30 hours local time at the Ministry of Health & Quality of Life and Public Opening being on the same day at 13.45 hours.

Following representations received from bidders, an addendum No. 1 was posted on PPO's website on 14 January 2015 and same was issued to all

bidders, who had accessed the site and downloaded the bidding documents.

B. Evaluation

The Bid Evaluation Committee was composed of:

Dr. (Miss) Noorjehan. Joonas	Head of Biochemistry Services, Central Health Laboratory, Candos (Chairperson)
Dr. (Mrs.) Vinita Devi Poorun	Consultant in Charge paediatrics, SSRN Hospital
Dr. Govindranath Sudesh Dewnarain	Consultant Internal Medicine, Victoria Hospital
Dr. How Chan How Cheong Wen	Specialist/Senior Specialist General Medicine, Flacq Hospital
Dr. Satish Rughoo	Community Physician, NCD Coordinator, Dr. A. G. Jeetoo Hospital
Mrs. Sadhna Hunma	Principal Clinical Scientist, Biochemistry Department, Central Health Laboratory, Candos
Mr. P. Taucoor	Charge Nurse, Medical OPD, Victoria Hospital

List of Bidders and Prices read out as in Public Opening was as follows:

Bidder No.	Bidder	Bid Amount (Rs)
1.	Emmanuel Trading Services	24,300,000.00
2.	Harel Mallac Healthcare Ltd	20,062,080.00
3.	Ducray Lenoir Ltd	19,683,000.00
4.	Health Focus Ltd	29,866,926.00
5.	AVS Healthcare Ltd	13,665,000.00
6.	Pharmacie Tropicale Ltée	46,354,325.00
7.	Pharmacie Nouvelle Ltd	27,457,785.00
8.	FTM (Mauritius) Ltd	45,665,670.00
9.	Gi's Pharma Ltée – Offer 2(a)	23,696,086.82
9.	Gi's Pharma Ltée – Offer 2(b)	27,877,749.20
10.	Unicorn (MSJ Ltd)	38,039,220.00
11.	Xenobiotic Medical Ltd	20,805,120.00
12.	Advanced Healthcare Ltd	30,253,500.00
13.	VNS Diagnostics Ltd	26,122,500.00
14.	Global & Strategic Procurement Ltd	16,990,500.00
15.	IBL Healthactiv Ltd	26,730,000.00

During evaluation, the BEC established tables of conformity for all tenderers, from which the Panel has drawn to establish the following comparative conformity tables for items 1 & 2 respectively:

3000 units of Gluco-meters of following specifications		
Specifications	Conformity Harel Mallac Rightest GM 700 Make: Bionime Manufacturer: Bionime Corporation Country of Origin: Taiwan	Conformity Ducray-Lenoir Gluco Navii Make: GHD Manufacturer: SD Biosensor Inc Country of Origin: Korea
(a) Able to perform around 100 tests consistently (and at a go) and user friendly.	OK	OK
(b) Compatible for use in all units of the health institutions, including neonatal units.	OK	OK
(c) Reliable (evaluated and cleared by FDA-USA or MHRA-UK or ISO 15197 certified: relevant reports or certificates to be submitted).	OK	Not FDA cleared. No ISO 1597 Certificate submitted.
(d) Have a warranty of at least 3 years	OK	OK
(e) Capillary filled test strip system.	OK	OK
(f) Automatic calibration or using calibrator chip.	OK	OK
(g) Sample type: capillary, venous and neonatal.	OK	OK
(h) Provision for alternative site testing	OK	OK
(i) Result type: Plasma calibrated and reported in mmol/L	OK	OK
(j) Sample volume: less than 5 µl	OK	OK
(k) Measurement time: up to 10 secs	OK	OK
(l) Measurement range: 2 to 27 mmol/L	OK	OK
(m) Haematocrit range 20-65%	OK	OK
(n) Operating temperature 15-40°C and humidity up to 85%	OK	Humidity not mentioned.
(0) Interferences and limitations of method must be provided in user manual/Kit inserts	OK	OK
(p) System must provide Quality control samples	OK	OK
(q) The glucosemeter should be provided in a case or bag and comprise one pricking device, ten lancets and user manual / guide leaflet and package inserts.	OK	OK
(r) The make of the glucosemeters and test strips proposed by the bidders should be available for the sole use in the health services of the Ministry of Health and Quality of Life.	OK	OK
(s) The make, manufacturer's name and country of origin should be printed /embossed on the primary packaging material by the manufacturer	OK	OK

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121,500 boxes of 50 test strips foiled or unfoiled or 60,750 boxes of 100 test strips individually foiled Test strips for determination of glucose· in blood compatible with item no. 1 with the following specifications:		
Specifications	Conformity Harel Mallac Rightest GM 700 Bionime Manufacturer: Bionime Corporation Country of Origin: Taiwan	Conformity Ducray-Lenoir Gluco Navii Make: GDH Manufacturer: SD Biosensor Inc Country of Origin: Korea
Packaging	boxes of 50 test strips unfoiled - OK	Boxes of 50 test strips - OK
Storage temperature: 15-30°C and humidity up to 85%.	OK	Humidity not mentioned.
Test strips must have a shelf life of at least 12 months at time of delivery of each consignment	OK	OK
The make, manufacturer's name, country of origin, manufacturing date and expiry date should be printed / embossed on the primary packaging material by the manufacturer.	OK	OK

The BEC concluded that:

(a) The BEC considers that the bids submitted by the lowest evaluated bidder for items 1 and 2 are fully responsive to tender requirements.

(b) The lowest evaluated bid for items 1 to 2 is as follows:

Item No	Bid No	Bidder	Amount (Rs)	Remarks
1 & 2	2.	Harel Mallac Healthcare Ltd	20,062,080.00	Lowest evaluated responsive offer

C. Notification of award

The Ministry of Health & Quality of Life through a letter dated 15 May 2015, informed the Applicant of the particulars of the successful bidder as follows:

Item No.	*Bidder*	*Address*	*Contract Price (Rs)*
1	*Harel Mallac Healthcare Ltd*	*18, Edith Cavell Street, Port Louis*	*Free of charge*
2	*Harel Mallac Healthcare Ltd*	*18, Edith Cavell Street, Port Louis*	*20,062,080.00*

D. The Challenge

On 15 May 2015, the Applicant challenged the award on the following grounds:

"Our bid value is Rs19,683,000.00 as compared to Rs20,062,080.00 for Harel Mallac Healthcare".

E. The Reply to Challenge

On 15 May 2015, the Public Body made the following reply to the challenge:

"We wish to inform you that the Bid Evaluation Committee has not retained your bid for the following reasons:

Item No.	*Remarks*
1	*(i) The equipment is not FDA cleared* *(ii) No ISO 15197 certificate has been submitted* *(iii) Humidity is not mentioned*
2	*Humidity is not mentioned*

F. Grounds for Review

On 27 May 2015, the Applicant seized the Independent Review Panel for review on the following grounds:

"1. Applicant was the lowest complying bidder in the bidding exercise inasmuch as the Applicant's bidding value under Item 2 was of Rs19,683,000 compared to the successful bidder's (Harel Mallac Healthcare Ltd) bidding value under Item 2 which was of Rs20,062,080.

2. Applicant did comply with all the requirements and specifications for Item 1 and Item 2 under the Description of Goods of the bidding documents.

3. Applicant is not satisfied with the information given by the Public Body by way of letter dated 21 May 2015 inasmuch as:

(i) Regarding the reliability certification

There was no obligation on the part of the Applicant, in the bidding exercise, to submit a ISO certificate as the specification for Item 1, described at subparagraph (c) of the Bidding Documents provide for Item 1 to be "Reliable (evaluated and cleared by FDA-USA or MHRA-UK of ISO15197 certified: relevant reports or certificates to be submitted)". Applicant did submit a Declaration of Conformity providing for the relevant certification, which falls within the ambit of the requirements for Item 1 being the "relevant reports" as required.

(ii) Regarding the Humidity requirement

The requirements for humidity, under both Item 1 and Item 2, respectively provided for under sub-paragraphs (n) and (a) of the Bidding Documents only provide for "… humidity up to 85%" and the Applicant did attach a Temperature and Humidity Test report to the bidding documents. At no point in time was the humidity requirement to be mentioned in the kit inserts and the user manual required for the bidding exercise."

G. The Hearing

Hearings were held on 22 July and 06 August 2015. Written submissions were made by the Applicant and Respondent on 29 July and 13 August 2015 and 12 August 2015 respectively. The Respondent was represented by Mr S. Boodhoo, Principal State Counsel and the Applicant by Ms J.

Mootoosamy, Counsel. Mr A. Peddadu from the Successful Bidder attended hearings, but was not supported by Counsel.

During hearings and in submissions, the Applicant maintained his position that

> 1. The requirement that "*evaluated and cleared by FDA-USA or MHRA-UK or ISO 15197 certified: relevant reports or certificates to be submitted"* was interpreted to mean that reports were acceptable as evidence of conformity to ISO 15197, and
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> 2. In regard to the requirement "*Operating temperature 15-40°C and humidity up to 85%" for* item 1 and *"Storage temperature: 15-30°C and humidity up to 85%"* for item 2, the equipment proposed by the tenderer were fully compliant, but that the Ministry of Health & Quality of Life had not specifically asked in the bid documents that these should be mentioned in the user manual or kit inserts.
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> The Ministry of Health & Quality of Life maintained the findings and conclusions of the Bid Evaluation Report.
>
> Also during hearings the Respondent stated that the letter from the Ministry of Health & Quality of Life to the Applicant dated 21st May 2015 should be considered as the final reply to the challenge, and therefore the Application for Review received on the 27th May was within time limits.

H. Findings

It should be obvious to all but the less informed of laymen that in the requirement "*evaluated and cleared by FDA-USA or MHRA-UK or ISO 15197 certified: relevant reports or certificates to be submitted", relevant reports* could only refer to clearances by the US **Food and Drugs Administration** or the UK **Medicines and Healthcare Products Regulatory Agency (MHRA)** and that conformity with any standards is evidenced by a certificate from an accredited agency. The Applicant cannot show conformity with ISO 15197 through self-assessment and report, and a prospective supplier of medical equipment cannot be unaware of this. Also, at no time did the Applicant attempt to show that his equipment conformed to any national (Korean) standards. It would be

hazardous indeed to place any confidence in the quality of this equipment.

In regard the absence of mention of humidity restrictions in user manuals and kit inserts, the Panel tends to agree with the Applicant that *"….At no point in time was the humidity requirement to be mentioned in the kit inserts and the user manual required for the bidding exercise."* The Applicant has argued that his equipment did conform to these requirements, and the fact that humidity restrictions were not mentioned in the accompanying literature was not an indication of the quality of the equipment. The Panel only wishes to draw the attention, for future use, of the Ministry of Health & Quality of Life to the necessity of specifying anything that it considers important in the tender requirements. In view of the fact that items 1 & 2 (testing equipment and compatible test strips) cannot emanate from different manufacturers, the Panel does not intend to delve further in this issue.

I. Decision

For the above reasons, the Panel is of the view that there is no merit in this Application.

However, the Panel cannot ignore the peculiar pricing of the successful bidder, which has offered item 1(testing equipment) free of charge, as is common practice in retail. As his final bid price is comparable to that of most of the tenderers, this means that the price for both items has been charged to item 2 (test strips). It may be reasonably expected that the requirements for test strips may increase. Anyone familiar with gluco-meters would be aware that the testing equipment will be used for as long as they last, but that each test strip can be used only once. The latter being a consumable, there is a high probability of further orders for as long as the equipment still work, as is evidently the expectation of the Successful Bidder. In this case, if the unit price of test strips should be calculated from the tendered price, the Ministry of Health & Quality of Life would pay approximately twice its price. A new tender for test strips would be meaningless, as only one manufacturer could supply strips compatible with the equipment in use.

The Ministry of Health & Quality of Life can get round this by negotiating an appropriate unit price that would be applicable only in

case of further orders, should those become necessary. This would not change this tender exercise, as the bid price and the contract price would not be altered.

(R. Laulloo)

Chairperson

(V. Mulloo)

Member

(R Ragnuth)

Member

Dated 17 August 2015