PUBLIC CONTRACTS REVIEW BOARD

Case 2011 – CT 2323/2023 – Supplies - Tender for the Supply of Sterile Disposable Urinometer with Urine Collection Bag

12th June 2024

The tender was issued on the 26th October 2023 and the closing date was the 19th December 2023.

The estimated value of this tender, excluding VAT, was € 148,761.93

On the 29th April 2024 OK Medical Limited filed an appeal against the Central Procurement and Supplies Unit objecting to the decision to reject their tender as it was deemed to be technically non-compliant.

A deposit of € 744 was paid.

There were fourteen bids.

On the 16th May 2024 the Public Contracts Review Board composed of Dr Charles Cassar as Chairman, Dr Vincent Micallef and Mr Lawrence Ancilleri as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – OK Medical Ltd

Dr Calvin Calleja	Legal Representative
Dr Krista Refalo	Legal Representative
Mr Josef Cachia	Representative
Mr Donald Attard	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Solange Vella	Chairperson Evaluation Committee
Ms Josette Camilleri	Secretary Evaluation Committee
Mr Edmond Balzan	Evaluator

Preferred Bidder – Drugsales Ltd

Dr Douglas Aquilina	Legal Representative
Mr Desmond Bell	Representative
Mr Reuben Demanuele	Representative

Dr Charles Cassar Deputy Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Krista Refalo Legal Representative for OK Medical Ltd (OK) stated that this appeal was on technical not legal grounds, namely that it is contested that the flow in the device is not running freely. This is a clear case of a manifest error in the evaluation process. OK's offer needs to be re-integrated in the evaluation process. The video submitted by the Contracting Authority demonstrating the use of the product indicates that it is not being used properly.

Dr Leon Camilleri Legal Representative for the Contracting Authority said that the samples failed the test. The product is used in critical situation, like the ITU and failure could have serious repercussions. The evaluation was correctly carried out.

Dr Calleja Legal Representative for OK Medical Ltd requested that witnesses be heard.

Ms Carmen Tabone (225767M) called to testify by the appellant stated on oath that she was a Charge Nurse in the ITU at Mater Dei Hospital and had 34 years' experience in using urinometers. She had tested the samples herself but does not recall the bidders who had submitted samples. The sample shown to her was confirmed as the one submitted by OK. Witness explained how the urinometer was used and showed how the sample was non-compliant as the urine was not flowing into the device automatically but had to be manipulated. Urinometer is meant to work by gravity unaided and she had checked the samples personally.

Questioned by Dr Douglas Aquilina Legal Representative for Drugsales Ltd, witness said that if the clamp on the device was closed there would be no flow. She had viewed the video produced by OK and said that the urine should flow by gravity without any pressure being applied. The problem became more serious if the patient was oliguric. Having to 'milk' the tube took more time, could harm patients and increased the risk of infection.

Questioned by a Board member witness stated that three devices were tested over a period of time by different nurses on different patients.

Questioned by Dr Camilleri witness stated that the effect on patients could be serious if not continually supervised. The device was used in ITU; High Dependency Unit; 1 to 1 cases and normal patients.

Mr Edmond Balzan (472665M) called to testify by the appellant said that he was an evaluator of medical devices with previous experience of testing urinometers. The sample device visually looked right when it was sent for testing. Samples were requested from 11 bidders only – three were not requested as their bids were very high. Three samples all produced by the same Chinese manufacturer failed and they all had an identical problem. The video on the OK sample was produced in the presence of other witnesses. The samples were tested on actual patients.

In reply to a question, witness explained the procedure of how the tests were done and said that usually three tests were carried out.

Mr Donald Attard (304763M) called to testify by the appellant stated on oath that he has been employed as a Sales Executive by OK since November 2023. He qualified as a Charge Nurse in 1993. He carried out a demonstration of use of urinometer sample using water instead of urine. Pressure through a syringe was used to push liquid into the chamber. If the clamp was closed, then obviously liquid did not flow.

Questioned by Dr Camilleri, witness confirmed that the pressure from a syringe is higher than the normal flow of urine.

In reply to a question from Dr Aquilina, witness said that the demonstration carried out today was exactly the same as when they had first tested the device.

Mr Josef Cachia (160084M) called to testify by the appellant stated on oath that he a Pharmacist by profession and Chief Operations Officer at OK. He noted that the top of the clamp was not visible on the video produced by CPSU. The product in question had been sold to St James' Hospital on a one-year contract with positive comments.

Questioned by Dr Camilleri, witness confirmed that the only item not showing on the video was the clamp on the patient's side but it was clear that the tube leading to the chamber was full. He said if the clamp is closed the flow would cease.

Mr Edmond Balzan (472665M) called to testify by the Contracting Authority stated on oath that there is a manufacturer of this type of equipment which produces urinometers under three different brands and all three display the same defect. In a previous testimony it was not mentioned that the device has a non-return valve. Using a syringe to push the fluid causes greater pressure which is unlike the natural flow of urine. The clamp was open at all times during testing and the nurses testing this equipment are highly experienced.

Questioned by Dr Calleja, witness stated that the procedure followed when evaluating was that first it tested the product of the cheapest bid then followed by that of OK. The evaluators do not tell the testers the name of the bidder or give any indication of origin of equipment. All identifying marks are removed.

This concluded the testimonies.

Dr Calleja referred to Clauses 2.5, 2.7 and 2.11 of the technical specifications on which this appeal hinged and according to which the OK offer was not complaint due to the lack of flow. However, before dealing with this point there is a legal point to put before the Board, namely the test of manifest error of assessment. PCRB Case 1943 well covered this point. The origin of this test goes back some 40 years and was adopted by the CJEU in cases 56/77 (para 20), 2145/98 (para 147) and 3C-300/07 (para 77) all dealing with the broad margin of discretion where there is a manifest error. These cases trickled down to local case 46/2014/1 *Cherubino vs CPSU* and a prior 2013 case. The Courts recognize that the experience and knowledge is in the hands of the evaluation committee however there can be a case for the decision being changed. In PCRB Case 1961 the Board found that there was a case of manifest error. In this case all the Board needs to do is to change the wording. Substantial proof has been provided that the product of the appellant is compliant with documentation, a video recording and testimonies of experienced persons. The only proof provided that the product works was by the appellant with no proof provided by CPSU that it does not work. Appellant requests that the tender is re-evaluated.

Dr Aquilina said that if one referred to the specifications it is clear that the product offered did not meet them. According to the tender samples were required. These were tried out and failed. This is not a matter of ticking boxes. The CPSU through a video and testimonies proved their case whilst appellant failed to provide the necessary proof. There is no proof provided that the clamp was closed, and this was only raised to create doubts.

Dr Camilleri dealt first with the issue of the clamp and the fact that advantage was taken of the fact that the clamp was not visible in the video. Two very experienced witnesses stated otherwise and there can be no doubt on this point. The manifest error case quoted by appellant does not mean that because it happened once – a completely different case- it also happened here. Witnesses clearly explained how the equipment was tested and removed any possible doubts. The video and witnesses produced by appellant confirmed that pressure through a syringe was higher than that of a patient's natural action.

Dr Calleja in a final submission said that there is no way of knowing how the video was produced and on which samples. There also seems to have been a change of mind regarding the effects that the clamp had.

Dr Camilleri replied that the witnesses were consistent that the clamp was open throughout. Reactilab, another appellant, realised the weakness of their case and withdrew their appeal.

As there were no further submissions the Chairman thanked the parties and declared the hearing closed.

End of Minutes

The Board hereby resolves:

The Board refers to the minutes of the Board sittings of the 16th May 2024,

Having noted the objection filed by OK Medical Limited on the 29th April 2024 refers to the claims made by the same Appellant regarding the tender of reference CT2323/2023 listed as case No. 2011 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Krista Refalo & Dr Calvin Calleja
Appearing for the Contracting Authority:	Dr Leon Camillieri & Dr Alexia Farrugia Zrinzo
Appearing for the Preferred Bidder:	Dr Douglas Aquilina

Having also noted the letter of reply filed by Dr Alexia Farrugia Zrinzo and Dr Leon Camillieri on behalf of CPSU (hereinafter referred to as the Contracting Authority) filed on the 06th May, 2023

Having also noted the letter of reply filed by Dr Douglas Aquillina, Dr Mark Attard Montalto and Dr Samira Briffa on behalf of Drugsales Limited (hereinafter referred to as the Preferred Bidder) filed on the 06th May, 2024

Having heard and evaluated the testimony of the witness Ms Carmen Tabone, Charge Nurse in the ITU at Mater Dei Hospital, cited by the Appellant.

Having heard and evaluated the testimony of the witness Mr Edmond Balzan, evaluator cited by Appellant.

Having heard and evaluated the testimony and on-site demonstration of the witness Mr Donald Attard representative of OK Medical Limited cited by the Appellant.

Having heard and evaluated the testimony of the Mr Josef Cachia representative of OK Medical Limited cited by the Appellant.

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties.

Whereby, the Appellant mainly contends that:

A. The product submitted was compliant. This issue represents a clear case of manifest error in the evaluation process, indicating that the assessment was fundamentally flawed or incorrect.
B. The samples tested by the Appellant show the urine flowing freely

C. The video submitted by the Contracting Authority demonstrates improper use of the submitted product, further supporting the claim that the evaluation was not conducted accurately.

Whereby the Contracting Authority counter argued that:

A. The samples from OK Medical Ltd is not fit for its intended purpose and failed the test. Failure of the product in these critical settings could have serious, and potential repercussions.

B. The evaluation process was conducted correctly and in accordance with the necessary standards and protocols.

The Board takes note to the testimonies of the witness Ms Carmen Tabone, Charge Nurse in the ITU at Mater Dei Hospital and of the witness Edmond Balzan, evaluator whereby:

Both witnesses concurred on the method of using the urinometer, demonstrating the non-compliance of the sample provided by the appellant. They pointed out that the urine did not flow into the device automatically and instead required manipulation. The urinometer is intended to operate solely by gravity, without any assistance. Both, checked the samples, verifying the issue with the urine flow. This critical observation underscored the device's failure to meet the necessary operational standards.

The Board also noted the on-site demonstration conducted by Mr. Donald Attard. During this demonstration, it was observed that liquid remained in the pipe and that pressure from a syringe was used to push the liquid into the chamber. This demonstration corroborated the observations made by the witnesses. Regarding whether the clamp was closed, logic dictates that if the clamp was closed, all the liquid would remain in the pipe, preventing any liquid from reaching the chamber even with pressure or manipulation.

In view of the above the Board opines that Appellant's claim cannot be sustained.

This Board. concludes and decides that:

a) Does not uphold the Appellant's Letter of objection.

b) Upholds the Contracting Authority's decision in the award of the tender.

c) Directs that the deposit paid by the Appellant is not to be reimbursed

Dr Charles Cassar	**Mr Lawrence Ancilleri**	**Dr Vincent Micallef**
Chairman	**Member**	**Member**