PUBLIC CONTRACTS REVIEW BOARD

Case 1892 – CfT020-1378/22 – CPSU7428/22 – Supply of Povidone Iodine Non Adherent Dressings

21st July 2023

The Board,

Having noted the letter of objection filed Dr John L Gauci acting for and on behalf of ProHealth Limited, (hereinafter referred to as the appellant) filed on the 12th May 2023;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 22nd May 2023;

Having heard and evaluated the testimony of the witness Mr Duncan Griggs (Registered Nurse in the UK) as summoned by Dr John L Gauci acting for ProHealth Limited;

Having heard and evaluated the testimony of the witness Professor Richerd White (Professor of Tissue Viability in the UK) as summoned by Dr John L Gauci acting for ProHealth Limited;

Having heard and evaluated the testimony of the witness Mr Edmond Balzan (Member of the Evaluation Committee) as summoned by Dr Leon Camilleri acting for Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Ms Miriam Wubbles (Representative of Central Procurement and Supplies Unit) as summoned by Dr Leon Camilleri acting for Central Procurement and Supplies Unit;

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

Having noted and evaluated the minutes of the Board sitting of the 11th July 2023 hereunder-reproduced.

Minutes

Case 1892 – CfT 020-1378/22 – Supplies – Tender for the supply of Povidone Iodine Non-Adherent Dressings

The tender was issued on the 8th November 2022 and the closing date was the 29th November 2022. The estimated value of the tender, excluding VAT, was € 129,600.

On the 12th May 2023 Prohealth Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to the decision of the award on the basis that their offer was not according to the tender specifications.

A deposit of € 648 was paid.

There were three (3) bids.

On the 11th July 2023 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Ms Stephanie Scicluna Laiviera and Dr Vincent Micallef as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Prohealth Ltd

Dr John Gauci	Legal Representative
Mr Mark Bondin	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Rita Zammit	Chairperson Evaluation Committee
Ms Maria Curmi	Evaluator
Mr Edmond Balzan	Evaluator

Preferred Bidder – A M Mangion Ltd

Mr Ray Vella	Representative
Ms Tanya Carabott	Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr John Gauci Legal Representative for Prohealth Ltd said that Appellant was objecting on two ground, the first of which was that the Contracting Authority was claiming that his product was inferior to the other bidder. There is no basis factually or legally for this claim; it is not mentioned in the tender and it is a totally subjective assertion. There is the difficulty of scientifically comparing tests, which are not mentioned in the tender anyway. Specification 1.1 merely mention that the dressings are to be used for wound dressing with no other restrictions. The further restriction is that the product literature states that no more than four dressings may be used together due to the likely ill-effects. There is no limit imposed in the tender and this is merely a precautionary advice but not a condition.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that the rejection letter gave a detailed reason why the bid was refused. The product offered did not meet the aim of the tender. Sample testing is a normal procedure and there is no point in ignoring the outcome of testing which is allowed by the Public Procurement Regulations (PPR). This decision was justified. The literature offered was not a recommendation but a conditional limitation.

Mr Duncan Griggs (UK PP 543326871) called to testify by the Appellant stated on oath that he is a registered nurse in the UK and is a consultant specialising in medical devices with special relevance to the skin care industry. He has worked in iodine dressings since the 1990s. He explained that comparative exercises are difficult and he could not comment on the test carried out in this case as no information was available to him and different persons may come up with difficult results. He is not an expert on clinical trials but can state that the best method of testing is through a controlled case study. Trying out a product is not the same as evaluating it. The product offered by Appellant is a simple product using old technology. There is no obvious difference between the products offered

by the two bidders which are generally used as first line primary wound dressing for superficial use. The product MEGHdin has been in use for some eight years and is easily available in the UK. The Instructions for Use lists four conditions for use but the limit of four dressings, according to the witness, is something that is subject to clinical decisions as it is only advisory.

Questioned by Dr Camilleri, witness stated that he was assisting Prohealth Ltd with sourcing of products; it is quite common to have precautions or warnings on product use – he understood that the limit on number to be used is advisory and generally up to the clinician to decide.

Professor Richard White (UK PP 141212566) called as a witness by the Appellant testified on oath that he is a professor of tissue viability in the UK with some 50 years involvement with dermatology and wound care including use of iodine dressings. This experience includes research, publications and clinical trials on wound care. Regarding MECHdin this must conform with the CE mark regulations and requirements. Although not having used it, witness said that he could imagine how it will perform as it has to conform to standards requirements. One must rely on the clinician using it for maximum effect. However, there are different grades and criteria of wound infection and one cannot judge on the basis of one or two tests. Witness has not seen the product MEGHdin and he has no relationship with its manufacturers or with Prohealth. Regarding the use of dressings being limited to four, witness stated that in his view the key word is recommendation – it is not unusual for manufacturers to issue guidance on use of a product – he would put no real point to it.

Mr Edmond Balzan (472665M) called to testify by the Contracting Authority stated on oath that he was one of the evaluators, specialising on medical devices. He explained that in the case of a large wound it would be difficult to stick to just four dressings to cover it. The sample in this tender was tested by an end-user.

In reply to questions from Dr Gauci witness said that the sample test was not a comparison exercise and that the tender did not make any reference to any limitation on the number of dressings. Witness acknowledged that Prof White in his testimony said that it was up to the physician to decide but this would put the end-user at risk. Prof White recommended the product Inadine with which he had connections.

Ms Miriam Wubbles (311966M) asked to testify by the Contracting Authority said on oath that she has since 1987 been a senior tissue nurse tending to all types of wounds. She explained that new products are tested not for comparative purposes but to assess efficacy and facility of use. The product offered by Appellant was not consistent in the level of dampness of the dressings and the outcome on the sample tested on a wound was not satisfactory. The object of the dressings is to reduce the risk of infection and it is important to judge a sample judiciously. If a dressing is not efficacious there is a risk of a patient not using it when given to him to use or that there would be dangerous outcomes. The sample tested could lead to complications arising. The size of wounds vary and the limit of four dressings leaves large wounds at the risk of complications.

Questioned by Dr Gauci, witness confirmed that she did not form part of the evaluation team. She tried the sample on one patient infected with a diabetic ulcer and as the result was unsatisfactory she stopped the tests there. The wound was cleaned and the sample tried over two days according to the manual provided but there was no improvement.

In reply to questions from Dr Camilleri, witness said that she cleaned the wound herself and applied the dressing – the result she expected turned out to be different as the bacteria control did not

improve. It was the Department of Contract which insisted that the size of the dressings should be 5cm x 5 cm; this meant that one had to make a visual estimation of the size of the wounds.

This concluded the testimonies.

Dr Gauci referred to the testimonies heard from the various witnesses. It was clear that the sample test was not part of the tender requirements and it was only tested on one patient which contradicts what the experts said. The Appellant's submissions conform to the tender requests. This product has been in use in the UK for over 30 years. The grievances have been dealt with and supported by the witnesses produced.

Dr Camilleri said that sample testing is allowed by the PPR and is used regularly. Four witnesses have been heard. The first confirmed that Prohealth were his clients and his testimony is therefore dubious. Prof White clearly stated that he has never seen this product; Ms Wubbels is very competent and an expert in her sector – she tested the product which was not up to requirements and there was no improvement in her patient. Further a condition has been imposed by the limit of four patches – this cannot work as amply indicated by the technician in her testimony. There would be serious consequences if the product is not good enough. The appeal should be denied.

There being no further submissions the Chairman thanked the parties and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 11th July 2023.

Having noted the objection filed by ProHealth Limited (hereinafter referred to as the Appellant) on 12th May 2023, refers to the claims made by the same Appellant with regard to the tender of reference CfT020-1378/22 (CPSU 7428/22) listed as case No. 1892 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr John L Gauci
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo

Whereby, the Appellant contends that:

a) 1st grievance – Reason given for the technical non-compliance is both factually and legally unfounded –

Indeed, as will be amply demonstrated, the product supplied by Objector is completely in conformity with all the tender specifications and whilst the Contracting Authority cites specification 1.1., it does not in any manner indicate how this specification was breached. The product supplied is, in fact, indicated to be used as an antibacterial primary wound dressing as per the same specification and is in conformity with all the other technical specifications stipulated in the tender.

b) 2nd grievance – The exclusion on the basis that "Sample submitted when tried on patients did not provide the same outcome in managing superficial infected wounds as the previous Povidone Iodine dressing" is illegal in that it cites an entirely subjective exercise which was not even contemplated in the tender document –

It is evident that the Tender Document did not provide for any comparative exercise upon sample submission. Indeed, it is a well known principle of public procurement that bidders cannot be excluded for a reason which is not contemplated in the tender document itself or at law. Neither the tender document nor the law provide for the comparative exercise (if ever there was a credible one), between the products offered by the bidder and those offered by the incumbent, which is being cited by the Contracting Authority to justify Objector's exclusion.

Reference is made, inter alia, to a decision of the Court of Justice of the European Union in Case C-27/15, pursuant to a request for a preliminary ruling under Article 267 TFEU from the Consiglio di giustizia amministrativa per la Regione siciliana (Council of Administrative Justice for the Region of Sicily, Italy), made by decision of 10 December 2014, received at the Court on 22 January 2015, in the proceedings Pippo Pizzo v CRGT Srl, wherein it was expressly stated:

"36 In that regard, it must be borne in mind, first, that the principle of equal treatment requires tenderers to be afforded equality of opportunity when formulating their tenders, which therefore implies that the tenders of all tenderers must be subject to the same conditions. Second, the obligation of transparency, which is its corollary, is intended to preclude any risk of favouritism or arbitrariness on the part of the contracting authority. That obligation implies that all the conditions and detailed rules of the award procedure must be drawn up in a clear, precise and unequivocal manner in the contract notice or specifications so that, first, all reasonably informed tenderers exercising ordinary care can understand their exact significance and interpret them in the same way and, second, the contracting authority is able to ascertain whether the tenders submitted satisfy the criteria applying to the contract in question (see, to that effect, judgment of 6 November 2014 in Cartiera dell'Adda, C-42/13, EU:C:2014:2345, paragraph 44 and the case-law cited).

37 The Court has also held that the principles of transparency and equal treatment which govern all procedures for the award of public contracts require the substantive and procedural conditions concerning participation in a contract to be clearly defined in advance and made public, in particular the obligations of tenderers, in order that those tenderers may know exactly the procedural requirements and be sure that the same requirements apply to all candidates (see,

to that effect, judgment of 9 February 2006 in La Cascina and Others, C-226/04 and C-228/04, EU:C:2006:94, paragraph 32)

…

42 As has been pointed out in paragraph 39 of the present judgment, a contracting authority must comply strictly with the criteria which it has itself established. That consideration applies a fortiori where an exclusion from the procedure is concerned.

…

44 In view of the principle of equal treatment and the obligation of transparency, which is its corollary, to which contracting authorities are subject pursuant to Article 2 of Directive 2004/18, Article 27 of that directive cannot be interpreted as meaning that it allows those contracting authorities to derogate from the strict obligation to comply with the criteria which they have themselves established."

c) 3rd grievance – that without prejudice to the above, any such comparative exercise has no scientific and/or objective value unless carried out under strict controlled conditions

Without any prejudice to the above considerations, the comparative exercise allegedly carried out by the Contracting Authority to compare the management of superficial infected wounds of patients when using the sample submitted by Objector with that submitted by the incumbent does not have any scientific and/or objective value, since - as will be amply explained and demonstrated - for such a comparative exercise to have a scientific and conclusive basis, it needs to be conducted in a controlled environment and under specific conditions, including a rigorous documented randomized approach.

d) 4th grievance – that any precautionary advice contained in the product literature cannot be used to exclude objector –

Although it is a well-known tenet of public procurement that Bidders cannot subject their bids to unilateral conditions, the precautions contained in the product literature are not tantamount to a bidder's reservation but rather they are to be construed as precautions and contraindications which are statutorily required by the regulatory and licensing bodies. Indeed, and without prejudice to the above, the Tender document did not contain any specification which prohibited bidders from including, in their technical literature, precautionary advice to alert users, medical practitioners and administrators in respect of the dangers of the administration of harmful doses of iodine.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 22nd May 2023 and its verbal submission during the hearing held on 11th July 2023, in that:

a) First Grievance -

The objector claims that clause 1.1 was cited but the reason does not indicate that such clause was breached and insists that the product is in conformity with such clause. CPSU submits that this clause was effectively breached since after sample testing it was found that the product offered was not effective for its purpose. The fact that the literature of a particular product states that the product is an antibacterial primary wound dressing does not automatically mean that the product is compliant. Sample testing serves so as to determine whether the product is adequate for the required purpose or not. As will be further explained and testified during the sitting, the product was tested by Ms. Miriam Wubbels, Tissue Viability Nurse with vast experience who found the product not as effective as it should be.

b) Second Grievance -

In this second grievance the objector states that the bidders cannot be excluded for reasons not mentioned in the tender or at law, and that the tender document did not cater for a comparative exercise with the incumbent contractor's product. CPSU rebuts strongly to the above as sample testing has been long recognised by this Honourable Board as one of the most effective methods of evaluation. The below are 2 examples from numerous decisions where sampling was instrumental for a proper, correct and fair evaluation process:

"Case 1804 - Most relevant to this, was the demonstration provided by Mr Jesmond Seychell, which proved without a shadow of a doubt that the offer as submitted by the Preferred Bidder; was compatible with the requirements and objectives of the tender procedure. Also, a high number of samples were tested during the evaluation stage."

"Case 1660 - The Fact that; 1) Ms Wubbels has 30 years experience in the field including 10 years in tissue viability, 2) the samples were tested in different scenarios, removed any subjectivity"

Secondly, the product was not subject to a comparative exercise with that of the incumbent but was tested for efficiency and effectiveness for its use. The comparison was used as an example to explain that the offered product was delaying wound healing. This was clearly explained in the reason for rejection.

c) Third Grievance -

CPSU reiterates that the evaluation was not a comparative exercise but a normal evaluation where sample testing is carried out. A comparison is obviously made by the end user since as professional knows how the product should work on the patient and thus compares its results with the results that are usually expected. CPSU refers to the submissions to the above grievances and submits that sample testing by end users has long been recognised in our system. What is being proposed by the objector; i.e, that the testing has to be done in controlled environment under specific conditions, including a rigorous documented randomised approach, is an unnecessary burdensome and ineffective method which is only being proposed to discredit the evaluation and not because

it is required at law or for the purpose of a diligent evaluation process. Moreover, CPSU submits that the product will be used by end users in hospitals and clinics, therefore there is no better sample testing than by the users themselves who will be using the product on our patients.

d) Fourth Grievance -

CPSU submits that the condition in the product literature of the objector that "not more than 4 dressings are to be used at any one time" was not a precautionary advice but an imposed condition which would limit the use of the product. This product is procured in sizes of 5cm x 5cm so that it can be used on small wounds and so that multiple dressings can be used on wounds of different size as the need would require. Large wounds or burns would require multiple dressings, more than 4 in frequent instances. Thus, the condition that not more than 4 dressings are to be used at one time is an unnecessary limitation which limits the use of the product which was not limited to small wounds.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances.

As stated by same appellant during the hearing, the first three grievances can be 'grouped' into one, with its subject matter being the sample testing performed on their product. The fourth grievance then delves into the matter of the technical literature submitted.

Initially, this Board will analyse and decide on the issue of the technical literature submitted.

a) Technical Literature grievance –
   i. the bone of contention in reference to this grievance is whether the literature submitted by the Appellant is creating a 'condition', of a mandatory nature on the use of their product or whether such clauses are to be deemed and taken as a recommendation.
   ii. Both witnesses summoned by the Appellant, Mr Duncan Griggs and Professor Richard White seemed of the opinion these clauses are to be interpreted as *"…. something that is subject to clinical decisions as it is only advisory"* and *"it is not unusual for manufacturers to issue guidance on use of product"*.
   iii. On the other hand, Mr Edmond Balzan, a member of the evaluation committee, stated that, *"in the case of a large wound it would be difficult to stick to just four dressings to cover it."* Since their interpretation of the technical literature was that this was a condition which was being imposed by the appellant, the product provided was not fit for purpose. Moreover, he stated that *"Professor White, in his testimony said that it was up to the physician to decide but this would put the end-user at risk"*.

iv. Following such conflicting testimonies, this Board will make direct reference to the Technical Literature submitted. In the "Frequency to change" section the following is stated *"There are four **conditions** in which the dressing may be required to be changed* …… ***Not more than four dressings to be used at any one time**"* (bold & underline emphasis added)

v. The Board, therefore, cannot but agree with the Evaluation Committee, that the submitted literature / product by the appellant is restricted, by way of a condition (not a recommendation) that not more than four dressings can be used at any one time.

Therefore, this Board does not uphold this grievance of the Appellant.

b) Sample testing grievance –

i. Since the other grievance has not been upheld, this Board will not be delving and deciding on this specific grievance. The Appellant's bid remains technically non-compliant.

ii. None-the-less, it is still opportune to point out the following:

A. As per General Rules Governing Tenders, article 16.3, sample testing is allowable.

B. Even though sample testing is allowable, it is this Board's opinion that such testing should be done in a more rigorous manner than what was done in this case. Since this is a product which is 'widely' used, such testing would seldom be reliable if the sample population is restricted to only 1 patient. Without entering into technical and statistical theories, such results would also risk being skewed if the patient selected for testing is diabetic.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

a) Does not uphold Appellant's Letter of Objection and contentions,

b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,

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

Mr Kenneth Swain	**Dr Vincent Micallef**	**Ms Stephanie Scicluna Laiviera**
Chairman	**Member**	**Member**