

PUBLIC CONTRACTS REVIEW BOARD

Case 2086 – CT2392/2023 – Tender for the Supply of Non-Absorbable Polymer Locking Cup Banks for Surgery -PPU

3rd March, 2025

The Board,

Having noted the letter of objection filed by Dr Matthew Paris and Dr Zack Esmail acting for and on behalf of **Pharma- Cos Limited**, (hereinafter referred to as the appellant) filed on the 22nd July, 2024;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo, Dr Leon Camilleri and Dr Audrey Marlene Buttigieg Vella acting for and on behalf the **Central Procurement and Supplies Unit [CPSU]** (hereinafter referred to as the Contracting Authority) filed on the 31st July, 2024;

Having heard and evaluated the testimony of the witness Ms Marianne Debono (Evaluator) as summoned by Dr Zack Esmail acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Mr Tonio Pace (Representative of Pharma-Cos Limited) as summoned by Dr Zack Esmail acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Ms Alison Gatt (Chairperson of the Evaluation Committee) as summoned by Dr Leon Camilleri and Dr Alexia J Farrugia Zrinzo acting for the CPSU;

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 27th February 2025 hereunder-reproduced.

Minutes

Case 2086 – CT 2392/2023 – Supplies – Tender for the Supply of Non- Absorbable Polymer Locking Clip Banks for Surgery - PPU

The tender was published on the 24th February 2024 and the closing date of the call for tenders was the 11th April 2024.

The estimated value of this tender, excluding VAT, was € 77,954.40

On the 22nd July 2024 Pharma-Cos Ltd filed an appeal against the decision of the Central Procurement and Supplies Unit to disqualify their offer on the grounds that it was not the cheapest offer satisfying the administrative and technical criteria.

A deposit of € 400 was paid.

There were four bids.

On the 27th February 2025 the Public Contracts Review Board composed of Dr Vincent Micallef as Chairman, Mr Lawrence Ancilleri and Mr Keith Grech as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma-Cos Ltd

Dr Zack Esmail	Legal Representative
Mr Tonio Pace	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Alison Gatt	Chairperson of the Evaluation Committee
Ms Bernice Gauci	Secretary of the Evaluation Committee
Ms Marianne Debono	Evaluator

Department of Contracts

Dr Audrey Buttigieg Vella	Legal Representative
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Dr Vincent Micallef Vice- Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Zack Esmail Legal Representative for Pharma-Cos Ltd stated that the two grievances on which appeal is based are that the offer of the preferred bidder is not fully compatible and that sensitive medicinal products require an enhanced evaluation. The tender is clear that the product has to be fully compatible whilst the second grievance is tied to the first due to the nature of the product which requires very delicate and more caution in evaluation.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit, the Contracting Authority, said that the Authority is entitled to procure what it needs without limiting competition. The tender must be open and the Evaluation Committee's role is to ensure that the product offered meets the requirements. The Authority felt that the recommended product meets the requirements and there is no reason not to accept it. It is up to the appellant to prove that the evaluation was not carried out correctly.

Dr Esmail noted that the tender request was that the product had to be 'fully compatible' and requested that witnesses be heard.

Ms Marianne Debono (283171M) called to testify by the appellant stated on oath that she is a Charge Nurse with experience in the Health Care sector and her paramount role was patients' safety. She was the sole evaluator and was not sure who the other members of the Evaluation Committee were. She explained how she carried out the evaluation and the purpose of the clips in surgery. Witness said that she only evaluated the cheapest offer. Referred to clause 2.8 in the tender specifications witness said that she had not seen any literature or certification that the product was fully compatible with the HEM-O-LOK applicator and explained that if the component parts come from different suppliers then they would not be fully compatible and they could create problems as the clips inserted in the body might not close tightly.

Questioned by Dr Camilleri, witness said that the evaluation was carried out following the tender specifications. The witness and surgeon had tried the sample clip and met requirements as it had functioned properly with the applicator. They had tested the bidder's clip and it had agreed with the applicator.

At the request of Dr Camilleri, witness demonstrated use of clip with applicator.

In reply to a further question from Dr Esmail, witness confirmed that the sample used by the surgeon on a patient was successful but if it was not 100% compliant there could be repercussions.

Mr Tonio Pace (12268M) called to testify by the appellant stated on oath that he has a nursing background going back to 1986 and has experience of serving in several different medical departments. Currently he is the Product Specialist of appellant company. He explained how the clips are used and the use of polymers so that there are no clashes with MRI examinations.

In the case of titanium one has the tactile feedback which gives the assurance that the clip is good for purpose. Appellant has been dealing in this product for many years. Witness said he is comfortable that HEM-O-LOK is 100% compatible as both applicator and clips fit each other giving better security and safety. Validation means that after testing, data ensures quality with no danger to patients. Compatibility means that one must have the applicator working hand in hand with the clip manufacturer. The implication is that the patient is bound to suffer if the product is not compatible. The preferred bidder's product is not validated.

In reply to questions from Dr Camilleri, witness said that by tactile he meant that you get the assurance that the clip has clicked. The applicator and clips produced by the appellant's supplier company have been in use for 50 years. He has no information on the product offered by the preferred bidder. Validation gives the assurance in black and white that the applicator and clip came from the same source. Witness is not aware if this was requested in the tender as he had not seen this document.

Ms Alison Gatt (372782M) called to testify by the Authority stated that the Evaluation Committee consisted of her as Chairperson, a Secretary and one Evaluator. The Committee relies on the medical and technical submissions for its decision. Once the evaluation is complete the report is prepared and everything is checked.

This concluded the testimonies.

Dr Esmail said that the important part of the testimonies is the safety aspect of the product. The tender itself asked for HEM-O-LOK. There is a risk if the product is mixed with other parts. If it is not validated it cannot be fully compatible and therefore there must be doubts on safety.

The need for enhanced evaluation in the case of sensitive products was emphasised in the V J Salomone Pharma Ltd Case (54/2012) and one must treat this product with great caution. Witness stated that the evaluation only checked the preferred bidder's product. If there is any doubt a fresh evaluation with a fresh team should be ordered.

Dr Camilleri said that the arguments regarding validation do not appear anywhere in the tender dossier – it is the principle of self-limitation that is clearly stated. The specifications are clear and the evaluator confirmed that the clip was tested and worked. The appellant claims that if the product is not validated it cannot be compliant. However, the Authority is aware that there are alternative sources which work on HEM-O-LOK and which meet the specifications. The tender specifies in clause 2.7 that the closure is confirmed and therefore clips must have clicked and closed. The appellant has no way of knowing if the preferred bidder's product is guaranteed as no testimony has been given on this matter so there is no reason for the appellant to state that the product is not compliant. Regulation 262 could always have been used if the appellant was not happy with the terms of the tender. If the functionality of the product is there why exclude it? Allegations have not been proven.

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 27th February 2025.

Having noted the objection filed by Dr Matthew Paris and Dr Zack Esmail for and on behalf of Pharma-Cos Limited (hereinafter referred to as the Appellant) on 22nd July, 2024, refers to the claims made by the same Appellant with regard to the tender of reference CT2392/2023 listed as case No. 2086 in the records of the Public Contracts Review Board.

Appearing for the Appellant:

Dr Zack Esmail

Appearing for the Contracting Authority:

Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri

Whereby, the Appellant contends that:

Whereas, by means of a letter dated 12th July 2024, the Appellant company was informed that that its offer was being rejected:

"Thank you for participating in the above-mentioned tender procedure. However, I regret to inform you that the tender submitted by your company was not successful since the criteria for award of this tender was the cheapest priced offer satisfying the administrative and technical criteria."

Whereas, by means of an email dated 15th July 2024, the DOC, following a request for information, confirmed that the manufacturer of the recommended bid is Anka Saglik Gerecleri Sanayi Ic ve Dis Ticaret Sti, with the Country of origin being Turkey;

Whereas, the Appellant company feels aggrieved by such a decision, and is hereby submitting its objection within the stipulated time-frame and accompanied with the relative payment (copy of confirmation of payment enclosed as DOC1), in accordance with inter alia article 270 of Subsidiary Legislation 601.03 (hereinafter the PPR), and this based on the following grievances:-

1. Product offered by recommended bidder is not "fully compatible"

The technical offer in Part 1 [2.8], held that:

- Must be fully compatible with HEM-O-LOK endoscopic applier
- N/A
- Mandatory

The emphasis is on the use of the terms "fully compatible". The DOC/Contracting Authority opted to use the broadest of terms - It could have used the term "compatible", and/or used language which shows that a product offered with the same traits of or which can be used with "HEM-O-LOK" would suffice - It did not, and it emphasised and qualified that the compatibility must be "fully", and thus any evaluation must be consistent with and compliant with the language of the tender;

The term "fully" is interchangeable with the term "entirely" or "wholly", and thus the compatibility must follow stringent validation protocols and be entirely in sync with the standards required by the tender, specifically provision 2.8;

It is the submission of the appellant company that, the bid by Krypton Chemists Limited [hereinafter "the recommended bidder"] has not been validated by the manufacturer of "HEM-O-LOK", and thereby it is definitely not "fully compatible" with "HEM-O-LOK";

In addition to the aforesaid, the product on offer by the recommender bidder fails to satisfy all the functional requirements for the intended use, and thereby the product can never be deemed to be "fully compliant" with "HEM-O-LOK";

The evaluation committee in this procedure has failed in its obligations in accordance with the principles of self-limitation, to evaluate the tender in accordance with the tender specifications. These principles have been confirmed on various occasions, including in the case in the names of Nexans France v European Joint Undertaking for ITER and the Development of Fusion Energy [T-415/10], wherein it was inter alia held,

'It must be borne in mind at the outset that where, in the context of a call for tenders, the contracting authority defines the conditions which it intends to impose on tenderers, it places a limit on the exercise of its discretion and, moreover, cannot depart from the conditions which it has thus defined in regard to any of the tenderers without being in breach of the principle of equal treatment of candidates. It is therefore by reference to the principles of self-limitation and respect for equal treatment of candidates that the Court must interpret the tender specifications';

2. Evaluation of medicinal products requires an enhanced evaluation

The product is used, inter alia for:

- For complex abdominal surgery
- N/A
- Mandatory

And thus whilst all evaluation must be done in an optimal way, wheresoever the product/service to be acquired is sensitive, it is fundamental that enhanced evaluation should be conducted;

The latter, has also been confirmed in a Court of Appeal decision, in the names of **V.J.Salomone Pharma Limited vs Direttur tad dipartiment tal-kuntratti et.**, whereby it was held that:

'Mhux biss, iżda f'kwistioni ta' natura delikata bhal ma hi l-oggett ta' dan il-kuntratt pubbliku u cioe' il-provvista ta' medicinali lill-pazjenti li ikun għaddew minn operazzjoni serja bhalma hi dik ta' trapjant ta' organi, il-Bord messu mexa b'iktar kamtela ...'

It is the submission of the appellant company that, the Evaluation Committee has failed in its obligation to conduct an appropriate and proper enhanced evaluation - this would have ascertained and confirmed that the product by the recommended bidder was not compliant;

In view of the above, it is hereby being requested that the decision of the evaluation committee is cancelled, and a newly composed evaluation committee is appointed to appropriately evaluate all bids;

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 31st July and its verbal submission during the hearing held on 27th February 2025, in that:

On the First Grievance - Product offered by recommended bidder is not "fully compatible"

The Objector in its first grievance refers to clause 2.8 of P.

part 1 of the technical specifications which states that "*Must be fully compatible with HEM-O-LOK endoscopic applier*";

The Objector differentiates between 'fully compatible' and 'compatible' and argues that for any product to be fully compatible with the HEM-O-LOK endoscopic applier, it must be validated by the HEM-O-LOK manufacturer;

The DOC and CPSU humbly submit that this grievance is unfounded and frivolous;

What the objector is suggesting is limiting the call for one brand and thus limiting competition, which as the objector is well aware runs contrary to the Public Procurement Regulations S.L. 601.03 (PPR) and to the general principles of public procurement and competition law;

The Court of Appeal has, in a recent decision in the names ***Krypton Chemists Limited vs Central Procurement and Supplies Unit***, emphasized on the principle of open competition:

34. Naturalment filwaqt li mbuwiex mistenni li l-awtorità kontraenti tnaqqas dawn ir-rekwiżiti drastikament sabiex b'hekk kull oblatur ekonomiku, anke dak li ma jkunx kapaci jidhol għall-kuntratt, ikun jista' jiebu sehem fis-sejba; min-naha l-obra però l-awtorità kontraenti għandha d-dmir li tistabbilixxi rekwiżiti li jkunu jistgħu jintlahqu minn għadd ta' operaturi ekonomici biex b'hekk ma tirrestringix il-kompetizzjoni għusta.

35. *Fit-tfassil ta' dawn ir-rekwiżiti, l-awtorità kontraenti ghandha dejjem timxi bir-riga tal-proporzjonalità. F'dan is-sens ghalbekk, kontra dak li tgħid is-CPSU fir-risposta tal-appell tagħha mbumwix minnu li l-principju tal-proporzjonalità jgħodd biss fl-evalwazzjoni tal-offerti. Tassew il-principju tal-proporzjonalità għandu jgħaddem ukoll f-istharrig ta' jekk rekwiżiti tekniċi li jkunu gen imposti fsejha, illi jafu jillimitaw is-sehem ta' oblaturi ekonomici, bumwix oggettivament ragonevoli fil-kuntest tal-iskop tas-sejha.*

36. *Kif tikteb il-Professor Sue Arrowsmith, f'pagna 579 tal-ktieb tagħha The Law of Public and Utilities Procurement (Volume 2):*

«Compliance with the principle that specifications must not be drawn up in such a way as to exclude products/works/services that meet an entity's functional requirements can often be achieved by formulating specifications in terms of performance or functional specifications rather than detailed requirements.»

The Contracting Authority indeed did not limit competition in its call since it did not request a branded product but a product which is fully compatible with a HEM-O-LOK endoscopic applier;

"Fully compliant" does not mean that it is manufactured or in some way endorsed by the manufacturer of the equipment but simply that it is fully compliant with that same equipment and not partially compliant;

Had the contracting authority required for some reason a product which is validated by the HEM-O-LOK manufacturer it would have requested so, however since there was no compelling reason for such a restricting requirement, in observance of the above cited principles, the contracting authority has requested a product which is fully compatible with HEM-O-LOK endoscopic applier. The evaluation process has concluded that the recommended bidder's offered product was fully compatible and thus there was no reason whatsoever not to accept the offer;

The General Rules Governing Tenders v4.9 in paragraph 5.6 even give room for the acceptance of an equivalent when a brand is stated in the tender requirements, let alone in the present circumstance where no brand is being requested and the request is only for full compatibility!;

DOC and CPSU humbly submit that on the basis of these reasons which will be further expounded during the sitting, this grievance should be rejected;

On the Second Grievance - Evaluation of Medicinal products requires an enhanced evaluation

In this grievance the objector states that Evaluation of Medicinal products requires an enhanced evaluation, alleging that in the present case the evaluation committee failed to conduct a proper and proper enhanced evaluation;

The Objector fails to give any reason for this grievance and this runs counter to regulation 271 of the PPR which states that the appeal "*shall contain in a very clear manner the reasons for their complaints*";

DOC and CPSU respectfully submit that since no reason for this grievance have been given in the letter of appeal, this grievance should be declared inadmissible;

Without Prejudice to the above stated, DOC and CPSU submit that the evaluation process was properly conducted and the product of the recommended bidder was tested by end users and thus there is no reason for a decision by this Honourable Board to refer this call for re-evaluation;

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 follows in their entirety.

The Appellant in this case has raised concerns regarding the evaluation process for a tender involving the procurement of Non-Absorbable Polymer Locking Clip Banks for Surgery - PPU. Specifically, the Appellant alleges that:

1. The Evaluation Committee failed to properly assess the compatibility of the preferred bidder's product.
2. The Evaluation Committee failed to conduct an enhanced evaluation.

The Public Contracts Review Board (hereinafter referred to as "the Board") has carefully considered the evidence presented, including the testimonies of the Appellant and the Respondent, as well as the underlying legal and procedural framework governing public procurement.

Allegation of Product Incompatibility:

The Appellant contends that the Evaluation Committee overlooked the fact that the product offered by the preferred bidder was not fully compatible with the specifications outlined in the tender document. The Appellant has sought to support this claim by producing documentary evidence and by summoning a representative of Pharma-Cos Limited, a direct competitor in the tender process, to testify regarding the incompatibility of the preferred bidder's product.

The Board acknowledges the testimony provided by the representative of Pharma-Cos Limited. However, the Board notes that Pharma-Cos Limited, being a competitor in the same procurement process, is not an independent or unbiased witness. As such, the Board considers that the Appellant has failed to provide sufficient objective evidence to substantiate the claim of incompatibility.

While the Board is sympathetic to the Appellant's concerns, it finds that the evidence presented does not conclusively prove that the preferred bidder's product was not fully compatible with the tender specifications. Therefore, the Appellant's first grievance is not upheld.

Failure to Conduct an Enhanced Evaluation:

The Appellant has also raised concerns about the Evaluation Committee's failure to conduct an enhanced evaluation due to the sensitive nature of the product involved in the tender process. This issue relates to the quality of the evaluation and the committee's adherence to best practices, whether the evaluation was a normal evaluation or as cited by the appellant an 'enhanced' form of evaluation, which, according to the Appellant, went amiss.

Upon examination, the Board has identified several flaws in the evaluation process that have led to significant procedural concerns. Apart from the sub-headings that will be cited by this Board hereunder, the Board also makes reference to the Evaluator's testimony which directly impinges on the quality of the evaluation.

To this effect, the Board refers to the minutes which highlights the following:

"...She was the sole evaluator and was not sure who the other members of the Evaluation Committee were. She explained how she carried out the evaluation and the purpose of the clips in surgery. Witness said that she only evaluated the cheapest offer. Referred to clause 2.8 in the tender specifications witness said that she had not seen any literature or certification that the product was fully compatible with the HEM-O-LOK applicator and explained that if the component parts come from different suppliers then they would not be fully compatible and they could create problems as the clips inserted in the body might not close tightly..."

The reproduction of the Evaluator's testimony in the cited minutes are, by her very admission, self-explanatory and points out to the following observations:

a. Lack of Meetings

One of the most troubling issues uncovered during the proceedings is the fact that the Evaluation Committee, although presided over by a Chair and a Secretary, never actually convened. This was confirmed by the testimony of Ms Marianne Debono. This result amply clear from the testimony of same as replicated

in the minutes of the Appeal's proceedings here-above. The lack of a formal meeting process indicates a breakdown in the procedural integrity of the evaluation process.

b. Understanding the Tender Process as Outlined in the ITT – Flawed Evaluation Sequence

The tender document is clear in its structure and delineates a specific chronological order for the evaluation process. Section 1 of the ITT, entitled "*Instructions to Tenderers*," lists the steps of the evaluation process, which are, *inter alia*, as follows:

- **(A) Eligibility Criteria:** The first stage is the review of the eligibility criteria to ensure that all bidders meet the fundamental requirements set out in the tender document.
- **(B) Exclusion (including Blacklisting) and Selection Criteria:** Following eligibility, the committee assesses whether any bidder is excluded based on blacklisting or other exclusion grounds. This stage also reviews the selection criteria.
- **(C) Specifications:** After the exclusion and selection criteria are assessed, the committee evaluates the bidders' technical proposals to ensure they meet the specifications outlined in the tender document.
- **(D) Financial Offer:** The financial offers are assessed last, only after the technical evaluation has been completed.

This sequence explicitly ensures that only those bids that are technically compliant move on to the financial evaluation stage. By separating the technical and financial evaluations, the ITT aims to prevent any undue influence of pricing on the initial review of technical capabilities. Although the Board understands the magnitude of the tenders' that the Contracting Authority deals with on a daily occurrence and the expedited manner in which the Contracting Authority deals with same, particularly in the realm of medical equipment, given also the urgent nature of product in demand, the Board cannot fail to ascertain that the process runs rigorously in accordance with the tender requirements elucidated by the, after all, Contracting Authority itself.

No derogation permissible by the tender document and in line with the Public Procurement Regulations and any ancillary legislation have been exhibited in the acts of these proceedings that provides the necessary comfort to this Board to depart from the established tender requirements.

c. Single Evaluator Issue

Another concerning issue identified by the Board is the fact that the evaluation was conducted by a single evaluator. As per the "*Standard Operating Procedures (SoP) Guidelines for Tender Evaluation Committees (TEC) Version 1.1 Department of Contracts*," a Tender Evaluation Committee should consist of at least three evaluators, or any odd number, unless otherwise approved by the Director of Contracts. This procedural

requirement is not simply advisory but is fundamental to ensuring fairness and transparency in the evaluation process.

The importance of multiple evaluators is to ensure a balanced and collective judgment, reducing the risk of bias and improving the objectivity of the evaluation. In this case, the evaluation conducted by a single evaluator was inherently flawed. The decision made by a single evaluator cannot be considered consistent with the best practices outlined in the relevant guidelines and regulations governing public procurement.

At this juncture, it is imperative to point out, once and again, that no derogation permissible by the tender document and in line with the Public Procurement Regulations and any ancillary legislation have been exhibited in the acts of these proceedings that provides the necessary comfort to this Board to depart from the established tender requirements.

Conclusion

While the Appellant's claim regarding the product incompatibility, was not substantiated to a sufficient degree, the Board finds that the evaluation process was marred by significant procedural flaws, including:

- The failure of the Evaluation Committee to meet and properly collaborate.
- The improper sequencing of the evaluation process, starting with the financial assessment before the technical evaluation.
- The failure to adhere to established procedural guidelines by relying on a single evaluator instead of a panel of evaluators.

The cumulative effect of these issues undermines the integrity of the tender evaluation process. As a result, the Board finds that the tender evaluation was not conducted in a manner consistent with best practices, fairness, and transparency.

Therefore, this Board, whilst not upholding the first grievance of the appellant, it upholds Appellant's second grievance.

The Board,

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

- a. Not to uphold Appellant's First Grievance;
- b. Uphold the Appellant's Second Grievance;
- c. Order the Contracting Authority to cancel the rejection letter;
- d. Revoke the recommendation for award made in favour of the Recommended Bidder;
- e. Order the Contracting Authority to reinstate the appellant company and through a newly composed Evaluation Committee, to re-evaluate the tenders;
- f. Direct that the deposit paid by Appellant to be reimbursed.

Dr Vincent Micallef
Chairman

Mr Lawrence Ancilleri
Member

Mr Keith Victor Grech
Member