PUBLIC CONTRACTS REVIEW BOARD

Case 2157 CT 2392/2023 – Tender for the Supply of Non-Absorbable Polymer Locking Clip Banks in Surgery -- PPU

13th October 2025

The Board,

Having noted the letter of objection filed by Dr Matthew Paris and Dr Zack Esmail, acting on behalf of Dalli Paris Advocates, acting for and on behalf of Pharma-Cos Limited (hereinafter referred to as the "Appellant"), filed on the 14th July 2025;

Having also noted the Reasoned Letter of Reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri, acting on behalf of 360 Legal, acting for and on behalf of Central Procurement and Supplies Unit (CPSU) (hereinafter referred to as the "Contracting Authority"), and Dr Audrey Marlene Buttigieg Vella, acting for and on behalf of the Department of Contracts (DOC), filed on the 23rd July 2025;Having noted the additional grievance filed by Dr Matthew Paris and Dr Zackariah Esmail on behalf of Pharma-Cos Limited on the 29th September 2025, following the Board's decree dated 25th September 2025 authorizing the submission of a third (additional) grievance;

Having also noted the letter of reply to the third (additional) grievance filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri on behalf of CPSU, and Dr Audrey Marlene Buttigieg Vella on behalf of DOC, dated 8th October 2025;

Having heard and evaluated the testimony of the witness Mr Charles Cini (evaluator and Consultant in Colorectal and Minimally Invasive Surgery) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited during the hearings on 25th September 2025 and 9th October 2025;

Having heard and evaluated the testimony of the witness Mr Tonio Pace (Company representative) as summoned by Dr Esmail Zack acting for Pharma-Cos Limited during the hearing on 9th October 2025;

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

Having noted and evaluated the minutes of the Board sittings of the 25th of September 2025 and 9th of October 2025, hereunder reproduced:

Minutes

Case 2157 CT 2392/2023 – Tender for the Supply of Non-Absorbable Polymer Locking Clip Banks in Surgery -- PPU.

The tender was issued on the 24th of February 2024, and the closing date was the 11th of April 2024.

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

On 14th July 2025 Pharma – Cos Limited (C7385) lodged an appeal against Central Procurement and Supplies Unit (CPSU) – the Contracting Authority, in accordance with Regulation 270 of the Public Procurement Regulations.

A deposit of €400.00 was paid.

There were four Bids.

FIRST DAY OF HEARING – 25th September, 2025

On the 25th of September 2025, the Public Contracts Review Board (PCRB), composed of Dr Vincent Micallef as Chairman, Dr Ing. Damien Gatt and Mr. Lawrence Ancilleri, as members, convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma – Cos Limited. (C7385).

Dr Matthew Paris – Legal Representative.

Dr Zack Esmail –Legal Representative.

Mr Tonio Pace – Company Representative.

Contracting Authority – Central Procurement and Supplies Unit (CPSU).

Dr Alexia J Farrugia Zrinzo – Legal representative.

Dr Leon Camilleri - Legal representative.

Mr Hristo Ivanov Hristov – Chairman.

Dr Rachel Abela – Evaluator. (online).

Dr Charles Cini – Evaluator. (online).

Mr. Matthew Sammut – Evaluator. (online).

Department of Contracts.

Dr Mark Anthony Debono – Legal Representative.

Recommended Bidder: Krypton Chemists Limited – Officially Declined Attendance.

Opening Statements

Dr Vincent Micallef, Chairman of the Public Contracts Review Board, welcomed the parties present, namely the Appellant Pharma–Cos Limited, the Contracting Authority—the Central Procurement and Supplies Unit (CPSU), and the Department of Contracts (DOC).

The Chairman, Dr Micallef, noted that this case had previously been heard by himself and Mr Lawrence Ancilleri, one of the two Board members. He referred to Article 734 of the Code of Organisation and Civil Procedure (COCP), observing that fairness suggested the issue of recusal should be raised. He stated they would have no objection to being excused if so requested.

All parties confirmed they had no objection to Dr Vincent Micallef and Mr Lawrence Ancilleri presiding over the hearing.

The Chairman then read the following into the record:

'That the board realised that this appeal has already been assigned and heard by two same members of the PCRB and informed all the parties about such issue which gives rise to abstention and/ or recusal in terms of act 734 d (ii) of the Code of Organisation and Civil Procedure (COCP) chapter 12 of the Laws of Malta.

The parties, i.e., the Appellant, the Contracting Authority and the Department of Contracts has flagged no objection whatsoever for the Board to be recused or the need to abstain, there by requesting the Board to proceed accordingly with the hearing'.

Dr Micallef then invited the Appellant's legal representative, Dr Matthew Paris, to deliver his initial submissions.

Before proceeding, Dr Paris inquired whether the Recommended Bidders had been invited to attend the sitting. The Chairman confirmed that they had and noted that Krypton Chemists Limited had officially declined attendance.

Initial Submissions

Initial Submissions by the Appellant (Dr. Matthew Paris)

Dr Paris submitted that the appeal concerns not only the exclusion of Pharma–Cos, but also the recommendation of award. He argued that the recommended bidder failed to meet the requirements of Article 2.8 of the Technical Offer Form. Accordingly, Pharma–Cos's exclusion was unjustified, since the recommended offer should have been rejected, and the award made instead to Pharma–Cos.

Initial Submissions by the Contracting Authority (Dr. Leon Camilleri)

Dr Camilleri recalled that the case had already been re-evaluated, after the Board had found that the first evaluation was conducted by only one evaluator. The Board had then recommended the appointment of a three-member Evaluation Committee. He stated that CPSU maintains that all functional specifications were fully compliant with the bid requirements.

Initial Submissions by the Department of Contracts (Dr. Mark Anthony Debono)

Dr Debono stated that the product submitted satisfied all the requirements of both the Contracting Authority and the CPSU.

Witness Testimonies

Testimony of Mr. Charles Cini (ID 6677G), summoned by Dr. Matthew Paris

Mr Cini, a Consultant Surgeon in Colorectal and Minimally Invasive Surgery, was an evaluator in the tender process.

The Evaluation Committee was composed of:

- Chairman: Mr Hristo Ivanov Hristov
- Dr Rachel Abela, Consultant
- Mr Matthew Sammut, Consultant Surgeon
- Secretary: Ms. Bernice Gauci

Mr Cini confirmed he had reviewed all documents submitted online. The Board was appointed between April and May, when all bids were received on the ePPS system. Four bids were submitted, of which three included samples. Pharma–Cos and Krypton Chemists were among the companies that provided samples.

Dr Paris drew attention to Article 2.8 of the Technical Offer Form, which required full compatibility with HEM–O–LOK.

Regarding Article 2.8, Krypton Chemists submitted the following:

1. Confirmation that the model offered complied with requirements: Yes
2. Details of the offer's specifications for the requisite: Refer to Doc 1–20
3. Reference in the technical literature: Blank

Dr Paris asked whether a clarification had been requested regarding the blank entry. Mr Cini explained that no clarification was sought, as the form itself stated "if applicable."

On the literature list, the request was for a product description, a price quotation, and proof of the product.

Referring to clauses 1.1–1.5, Dr Paris asked whether Mr Cini believed that "if applicable" should have been included in the Technical Offer Form. Mr Cini replied that the other company's documents appeared to meet all requirements. He further noted that, as a medical professional, he required more explanation regarding Note 3 of the Technical Offer Form.

Dr Paris explained that the tender document contained three notes:

- Note 1 – No rectification possible
- Note 2 – Rectification possible after submission
- Note 3 – No rectification possible, but clarification may be sought

He stressed that in this case, the Technical Offer Form fell under Note 3.

Dr Paris pointed out that the form was incomplete, as the relevant box was left blank, as were Boxes 2.1 onwards.

Request for an additional grievance brought forward by the Appellant

At this stage, Dr Paris suspended the witness's testimony and made the following request:

"*Dr. Paris suspended the testimony of Dr Charles Cini following his deposition and humbly requested this Board to authorise the Appellant to file an additional grievance in its letter of objection*."

He argued that the product was not only non-compliant but also incomplete and therefore should have been automatically excluded.

Contracting Authority's Objection (Dr Leon Camilleri) to the Appellant's request

Dr Camilleri objected, arguing that the time limit for filing new appeals had expired. He maintained that the "if applicable" wording meant the blank field was not mandatory.

"*The Contracting Authority is objecting to the appellant's request to file an additional grievance given that, the term within which such grievance should have been addressed has now lapsed. On a second note, the Contracting Authority also objects on the basis of the fact that the column entitled reference in the technical literature, where this is being stated, shown also encapsulates the term 'if applicable'*".

Department of Contracts Objection (Dr Mark Anthony Debono) to the Appellant's request

Dr Debono similarly objected, citing Regulation 271:

"*The Department of Contracts objects under Regulation 271, and further on the basis that the Appellant's interpretation elevates form over substance, which conflicts with the principle of proportionality in public procurement*."

Chairman's Ruling to the Appellant's request

The Chairman delivered the following ruling:

"Following the submissions made by all parties this Board upholds the appellant's request to entertain a new grievance because such request is being made, following fresh information that resulted during the testimony of Mr Charles Cini and therefore such information was not available at the time of addressing the appellant grievances".

Dr Paris requested adequate time to draft and submit the grievance, and to allow the other parties time to reply. He confirmed that the witnesses would not need to testify again, though one person should remain available online in case of further questions.

The Board granted:

"*The Board is hereby conceding five days from today, for the appellant to present its additional grievance and giving the Contracting Authority and the Department of Contracts a further five days from the date the grievance is officially received at the registry of the PCRB to submit their respective replies*".

The Board then scheduled the continuation of the hearing for Thursday 9th October 2025 at noon.

Conclusion of the Hearing

With no further arguments presented, Chairman Dr. Vincent Micallef thanked the parties and formally concluded the session.

End of Minutes for the First Hearing

SECOND DAY OF HEARING – 9th October, 2025

On the 9th of October 2025, at noon, the PCRB reconvened to continue considering the appeal following the first hearing held on the 25th of September 2025.

The Board was composed of:

- Dr Vincent Micallef – Chairperson
- Ing. Dr Damien Gatt – Member
- Mr Lawrence Ancilleri – Member

Attendance:

Appellant: Pharma-Cos Limited. (C7385).

Dr Zack Esmail – Legal Representative.

Dr Kayleigh Borg – Legal Representative.

Mr John Soler – Company Representative.

Mr Tonio Pace -- Company Representative.

Contracting Authority: Central Procurement and Supplies Unit (CPSU).

Dr Alexia Farrugia Zrinzo – Legal representative.

Dr Leon Camilleri – Legal representative.

Mr. Hristo Ivanov Hristov – Chairperson.

Dr Rachel Abela – Evaluator. (online).

Dr Charles Cini – Evaluator. (online).

Mr Matthew Sammut – Evaluator. Declined invite.

Department of Contracts.

Dr Audrey M Buttigieg Vella – Legal Representative.

Recommended Bidder: Krypton Chemists Limited – Officially Declined Attendance.

Opening Statements

Dr Vincent Micallef, Chairman of the Public Contracts Review Board, welcomed the parties present, namely the Appellant Pharma-Cos Limited and the Contracting Authority — Central Procurement and Supplies Unit (CPSU) and the Department of Contracts. The Chairman stated that this session is a continuation of the appeal before the Public Contracts Review Board.

Dr Esmail Zack, for the Appellant, stated that a new grievance had been submitted; however, there was another ongoing appeal. Since the five-day time limit was not observed, they requested that the Contracting Authority appeal to determine whether the Board should concede the CPSU's late reply. Dr Esmail declared that he was willing to accept any decision by the CPSU but did not agree with the legal reasoning presented during the appeal regarding the ten-day procedural term. He emphasized that any term granted by the Board could not be ignored in favour of the ten-day legal period.

Dr Leon Camilleri stated that the five-day limit was too short, given the correspondence exchanged between the parties. He further submitted that while their reply was technically late, it still fell within the ten-day term permitted by law, and he hoped the submission would be accepted.

The Chairman then made the following verbal ruling:

"The Board, after hearing the submissions of the Appellant and the Contracting Authority, notes the reasons and replies relevant to the Appellant's appeal, which includes an additional grievance. The reason for this additional grievance is that the reply was submitted late.

The Board does not agree with the position of the Contracting Authority, since Regulation 276, sub-article (c), issued by the same Contracting Authority, refers to the main appeal but not to any time limit established by this Board through an interlocutory decree. Acceptance of such a rule would render the orders of this Board superfluous and unsustainable.

This Board has the authority to regulate the appeal process in accordance with the Code of Organisation and Civil Procedure, Chapter 12 of the Laws of Malta. However, since the Appellant does not object and accepts the decision of this Board to admit the Contracting Authority's reply regarding the appeal and additional grievance, this Board shall accept the said reply."

Witness Testimonies

Testimony of Mr Tonio Pace (ID 12268M), Summoned by Dr Esmail Zack

Mr. Pace testified that he has long experience in the nursing profession and recently joined the distribution company Medina Healthcare, which has acquired Pharma-Cos Ltd. He worked in several

stations in the hospital. The product in question is the Polymer Hem-o-Lok — an unsolvable, implantable device classified as Class II. The clips are applied using pliers corresponding to their size.

Regarding the documentation for the Hem-o-Lok, Mr Pace stated that the documents were provided by the manufacturer, confirming that the only verified product is the Polymer Hem-o-Lok, with both clips and appliers guaranteed to be used together by the same company.

Cross-Examination by Dr Leon Camilleri

Mr Pace confirmed that he was not involved in the tender process, though he now represents the product. He had not seen the submission of the awarded bidder, **Krypton Chemists**, and had no access to its documents.

Testimony of Mr Charles Cini (ID 6677G), Summoned by Dr Leon Camilleri

Mr Cini, a surgeon specialising in abrasive surgery since 2001. This surgery is robotic were small holes and cameras are used instead of incisions. The other evaluators were Ms. Rachel Abela, Consultant Surgeon, and Mr Matthew Sammut, Surgeon. The products in question are clips used to close arteries in keyhole surgeries, which remain permanently in the body.

Dr Cini stated that he chose Krypton'**s** product after reviewing the samples and confirming that the different clip sizes were compatible with the appliers already available in the operating theatres. Krypton's clips were also the least expensive. Regarding compatibility, the preferred bidder submitted literature containing comparative studies demonstrating full compatibility.

The Chairman verified with Mr Cini that the sample tested was fully compatible with the Hem-o-Lok endoscopic applier and would be used in major abdominal surgery, as required.

Cross-Examination by Dr Esmail Zack

Mr Cini stated that the Chairman of the Evaluation Committee, who was present at the hearing, could provide the document containing the comparative studies submitted by the awarded bidder. The Chairman of the Evaluation Committee handed the document to the Board, leaving it to the Board's discretion to decide whether to share it.

Dr Esmail stressed the importance of accessing the document. After reviewing it, Chairman Dr Micallef decided to share the document, noting that Krypton Chemists had been invited but did not attend, and that neither the Contracting Authority nor any other party objected. Since the decision to award was based on analysis of this report, he ruled as follows:

"The Appellant requested that witness Mr Charles Cini produce the document referred to during testimony. The Contracting Authority handed this document to the Board. The Appellant requested a copy of it.

The Board notes that this document was submitted by the awarded bidder; however, as there were no objections — the recommended bidder having chosen not to attend despite being invited, and no objection from the Contracting Authority — the Board grants the Appellant the right to be given a copy of the document."

Mr Cini, referring to page 5 of the "Polymer Ligation Clip Equivalence Assessment Report", acknowledged that the table or text did not explicitly state full compatibility with the Hem-o-Lok. However, he confirmed that the document was produced by the manufacturer and was the only one submitted besides the surgeons' evaluation, as per clause 2.8 of the technical offer (Recommended Bidder, Note 1).

Re-Examination by Dr Alexia Farrugia Zrinzo.

Dr Zrinzo asked how Clause 2 of the bid was completed by the Appellant.

Mr Cini replied:

1. Confirmation by tender – Yes
2. Blank
3. Uploaded literature – Page 2

Final Submissions

Final Submissions by the Appellant (Dr. Esmail Zack)

Dr Esmail stated that the Appellant had three grievances:

1. Concerning full compatibility,
2. Concerning the evaluation process, and
3. Concerning the failure of the recommended bidder to complete the bid form properly.

He noted that in Krypton's bid, under *Part I – Technical Offer: Reference and Technical Literature*, the relevant section was left blank. The CPSU claimed this information was found elsewhere in the bid. However, this disregards the principle of self-limitation, as the technical offer form was accepted without excluding the recommended bidder.

Furthermore, the submitted document refers to the product as “equivalent,” not “compatible” or “fully compatible” as required by the tender. The manufacturer itself declared the product to be equivalent.

Dr Esmail argued that accepting equivalence in this case is unacceptable — as the product is invasive and critical for operations, full compliance must be ensured. Accepting an “equivalent” product introduces unnecessary risk.

Final Submissions by the Contracting Authority (Dr Leon Camilleri)

Dr Camilleri addressed the first grievance concerning compatibility. Witness Mr Cini confirmed that the evaluation was conducted by himself and two other surgeons. They physically tested the product with the Hem-o-Lok applier, found it functional, and recommended it.

Regarding compatibility, Dr Camilleri noted that Hem-o-Lok, as a brand, would not promote cheaper consumables from competitors. However, a document from the manufacturer submitted by the recommended bidder confirmed equivalence and compatibility with Hem-o-Lok.

He cited Clause 5.6 of the General Rules Governing Tenders:

“Where in the tender document a brand or label is quoted, it shall be understood that the Contracting Authority will accept equivalent standards, brands, or labels. However, it shall be the responsibility of the respective bidders, at the tendering stage, to prove that the standards, brands, and labels quoted are equivalent to those requested by the Contracting Authority.”

The evaluators did not rely solely on the document but conducted their own analysis and were satisfied that the evidence confirmed compatibility. The appellants, knowing the make of the recommended bidder’s product, could have submitted counterevidence but did not.

He argued that the grievance should therefore be dismissed, as both functional and documented compatibility were demonstrated, and the Evaluation Committee acted correctly under Clause 2.8.

Regarding the second grievance, Dr Camilleri emphasized that the Maltese State had appointed three qualified surgeons for a thorough technical evaluation.

As for the third grievance, he stated that Mr Cini had clearly indicated the pages confirming compatibility (pages 1–20). He also argued that Note 3 in the document is mandatory and cannot be altered, and although the information was entered in a different column, this was not a valid grievance. The evaluation and recommendation should therefore be upheld.

Replica by Dr Zack Esmail

Dr Esmail quoted:

"Bidders are to complete all the details requested in Part 1 of this document and the applicable section(s) from Part 2 of this document. Tenderers that fail to complete and upload the requested information will be deemed non-compliant and will not be considered further for final adjudication."

He argued that this document was not completed as required, and it is unacceptable to claim that the information could be found elsewhere. Doing so violates the **principle of self-limitation**.

Replica by Dr Leon Camilleri

Dr Camilleri responded that an evaluator would breach the principle of self-limitation only if he made a decision or recommendation based on material not included in the bid or not aligned with the tender specifications.

He clarified that "enhanced evaluation" in this context refers to the assessment of medical products by qualified doctors. The witness's lack of familiarity with certain procurement terminology did not mean the evaluation was flawed. The Evaluation Committee, which included a chairperson and secretary versed in procurement procedures, ensured compliance with regulations. When the witness said that Notes 2 and 3 were not within his expertise, he did not mean that the evaluation was improperly enhanced.

Conclusion of the Hearing

With no further arguments presented, Chairman Dr Vincent Micallef thanked the parties and formally concluded the session.

End of Minutes for the Second Hearing

Hereby resolves:

The Board refers to the minutes of the Board sittings of the 25th of September 2025 (first hearing) and the 9th October 2025 (second hearing).

Having noted the objection filed by Pharma-Cos Limited (hereinafter referred to as the "Appellant") on the 23rd July 2025 (and additional grievance filed 29th September 2025, following the Board's decree dated 25th September 2025) and refers to the claims made by the same Appellant with regards to the tender of reference CT 2392/2023 listed as case No. 2157 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Paris (first hearing only), Dr Zack Esmail, and Dr Kayleigh Borg (second hearing only)
Appearing for the Contracting Authority:	Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri
Appearing for the Department of Contracts:	Dr Mark Anthony Debono (first hearing only) and Dr Audrey M Buttigieg Vella (second hearing only)
Appearing for the Recommended Bidder:	None

Whereby, the Appellant contends with respect to:

Grievance 1: Product offered by recommended bidder is not "fully compatible"

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

2.8	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 highlights 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[1]", 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;
- The Contracting Authority, of its own volition, chose to qualify the level of compatibility required using the term "fully compatible", a phrase which denotes a stricter and more comprehensive standard than the more generic term "compatible". The plain and ordinary meaning of "fully"

[1] https://dictionary.cambridge.org/dictionary/english/fully

includes "entirely", "completely", and "wholly", leaving no room for partial or conditional compatibility.

- 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 the product by the recommended bidder is not "fully" compatible and is thereby in breach of the mandatory technical specifications.
- 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 been 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][2], 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';

Grievance 2: Evaluation of medicinal products requires an enhanced evaluation

- The product is used, inter alia for:

1.1	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.[3], whereby it was held that:
  '*Mhux biss, izda f'kwistjoni ta' natura delikata bhal ma hi l-oggett ta' dan il-kuntratt pubbliku u cioe' il-provvista ta' medicinali lill-pazjenti li ikunu ghaddew minn operazzjoni serja bhalma hi dik ta' trapjant ta' organi, il-Bord messu mexa b'iktar kawtela...*'
- 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.

[2] 20th March 2013
[3] Appell Civili Numru. 54/2012

- 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;

The Board notes the additional grievance (Third grievance) brought forward by the Appellant in the letter filed on the 29th September 2025 following the Board's ruling during the first hearing on the 25th September 2025.

Additional (Third) Grievance - Offer by recommended bidder is "non-compliant"

- Pharma-Cos respectfully submits that the bid of the recommended bidder is non-compliant, as its technical offer is incomplete and therefore incapable of rectification. The technical offer form itself explicitly required that:

  "*Bidders are to complete* ***all the details requested in PART 1 of this document*** *AND the applicable section/s from PART 2 of this document*."

  [added emphasis]

  Moreover, the form unequivocally stated that:

  "*Tenderers that* ***fail to complete*** *and upload the requested information will be* ***deemed as non-compliant*** *and will not be considered further for final adjudication*."

  [added emphasis]

  These conditions form part of the tender's governing rules and leave no room for interpretation.

- Through the testimony of Mr. Charles Cini, an evaluator, it was established that the recommended bidder did not fill in the information requested in relation to the references in the technical literature. In failing to submit such information, the bidder failed to provide a fully completed technical offer form. This omission cannot be considered minor, nor can it be subject to rectification, as the form was marked as having a note 3 status, therefore rendering it non-rectifiable under the established procurement framework.

- Consequently, the Evaluation Committee [hereinafter 'EC'] was bound by the tender's own terms to exclude the offer of Krypton Chemists Limited and to refrain from proceeding to its evaluation. By not excluding the offer at this preliminary stage, the EC not only disregarded the binding provisions of the technical offer form but also acted contrary to the tender rules that it was obliged to follow. The decision to proceed to evaluation despite such a material deficiency undermines the principles of equal treatment and transparency that must govern procurement procedures.

- This failure amounts to a breach of the self-limitation principle, which requires that the EC adhere strictly to the rules and conditions it has itself set out. Once the rules were clearly defined, namely,

that failure to complete and upload the requested technical details would result in automatic exclusion, the EC was legally precluded from ignoring or bending such rules. In defying these parameters, the EC compromised the integrity of the evaluation process and unlawfully admitted a non-compliant bid into further consideration.

The Board also noted the Contracting Authority's and DOCs **Reasoned Letter of Reply** filed on 28th July 2025 and its verbal submission during the hearing held on 25th September 2025 and 9th October 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 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[4] emphasized on the principle of open competition:

  34. Naturalment filwaqt li mhuwiex mistenni li l-awtorità kontraenti tnaqqas dawn ir-rekwiżiti drastikament sabiex b'hekk kull oblatur ekonomiku, anke dak li ma jkunx kapaċi jidħol għall-kuntratt, ikun jista' jieħu sehem fis-sejħa; min-naħa l-oħra però l-awtorità kontraenti għandha d-dmir li tistabbilixxi rekwiżiti li jkunu jistgħu jintlaħqu minn għadd ta' operaturi ekonomiċi biex b'hekk ma tirrestringix il-kompetizzjoni ġusta.

  35. Fit-tfassil ta' dawn ir-rekwiżiti, l-awtorità kontraenti għandha dejjem timxi bir-riga tal-proporzjonalità. F'dan is-sens għalhekk, kontra dak li tgħid is-CPSU fir-risposta tal-appell tagħha mhuwiex minnu li l-prinċipju tal-proporzjonalità jgħodd biss fl-evalwazzjoni tal-offerti. Tassew il-prinċipju tal-proporzjonalità għandu jitħaddem

[4] Court of Appeal, 15th February 2023 - 538/2023

ukoll fl-istharrig ta' jekk rekwiżiti tekniċi li jkunu ġew imposti f'sejħa, illi jafu jillimitaw is-sehem ta' oblaturi ekonomiċi, humiex oġġettivament raġonevoli fil-kuntest tal-iskop tas-sejħa.

36. *Kif tikteb il-Professur Sue Arrowsmith, fpaġna 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 restringing 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[5], 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 for 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;

[5] *5.6 Where in the tender document a standard, brand or label is quoted, it is to be understood that the Contracting Authority will accept equivalent standards, brands or labels. However, it will be the responsibility of the respective bidders, at tendering stage, to prove that the standards, brands or labels they quoted are equivalent to the standards, brands or labels requested by the Contracting Authority.*

- 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 "s*hall 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 by a committee of professionals 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;

The Board notes the Contracting Authority and DOC's Reasoned Letter of Reply for the additional grievance. The letter of reply is dated 8th October 2025.

On the Additional (Third) Grievance – Offer by recommended bidder is non-compliant

- The Objector in its third grievance states that the offer of the recommended bidder is not compliant as the technical offer form was not duly filled in.

- DOC and CPSU disagrees with the said grievance and submit that the column which was left blank was not mandatory as it stated *'if applicable'*:

- Moreover, and without prejudice to the above, DOC and CPSU submit that the information which was requested in the last column was provided in the 6th column entitled Details on the Offer's specifications for the respective requisite.

- The basic mandatory and substantive requirements requested in the technical offer form where thus respected and thus this third grievance should not be upheld.

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

First Grievance: Product offered by recommended bidder is not "fully compatible"

- The Appellant contends that the product offered by the Recommended Bidder is not "*fully compatible*" with HEM-O-LOK endoscopic applier as required by Clause 2.8 of Part 1 of the Technical Specifications. The Appellant argues that the term "fully compatible" denotes a stricter and more comprehensive standard than the generic term "compatible," and that only products validated by the HEM-O-LOK manufacturer can satisfy this requirement.

- This Board notes that this issue was comprehensively addressed in Case No. 2086, which involved an identical tender specification for the same product category. In that case, the Board examined the distinction between "*fully compatible*" and "*compatible*" and the Contracting Authority's submissions regarding the principle of open competition.

- The Contracting Authority in the present case has correctly submitted that requiring validation by the HEM-O-LOK manufacturer would effectively limit the call to one brand, thereby restricting competition contrary to the Public Procurement Regulations S.L. 601.03 and the general principles of public procurement and competition law. As emphasised by the Court of Appeal in the judgment *Krypton Chemists Limited vs Central Procurement and Supplies Unit*[6], the Contracting Authority has a duty to establish requirements that can be met by a number of economic operators so as not to restrict fair competition.

- The *General Rules Governing Tenders* v4.9, paragraph 5.6[7], provides room for the acceptance of an equivalent when a brand is stated in the tender requirements. In the present circumstances, where no brand is requested but only full compatibility, the evaluation approach taken by the Contracting Authority is consistent with procurement principles.

- The Board notes that the Evaluation Committee, composed of three qualified surgeons including Mr. Charles Cini, Dr. Rachel Abela, and Mr. Matthew Sammut, physically tested the Recommended Bidder's product with the HEM-O-LOK applier and found it to be functionally compatible. The

[6] Krypton Chemists Limited (C-8933) v. Central Procurement and Supplies Unit, Qorti tal-Appell, Rikors numru 538/23/1, 15 ta' Frar 2024.

[7] General Rules Governing Tenders v4.9, paragraph 5.6: "*Where in the tender document a standard, brand or label is quoted, it is to be understood that the Contracting Authority will accept equivalent standards, brands or labels. However, it will be the responsibility of the respective bidders, at tendering stage, to prove that the standards, brands or labels they quoted are equivalent to the standards, brands or labels requested by the Contracting Authority*"

witness Mr. Cini confirmed during testimony that the different clip sizes were compatible with the appliers already available in the operating theatres and that the Recommended Bidder submitted literature containing comparative studies between the Recommended Bidder's product and the product offered by the Appellant.

- While the Appellant submitted that the comparative studies document refers to the product as "equivalent" rather than "fully compatible," this Board finds that the functional testing conducted by qualified medical professionals, satisfies the requirement of full compatibility[8] within the meaning of the tender specifications. The Board concurs with the reasoning articulated in Case No. 2086, where similar arguments were raised and rejected.

- Accordingly, this grievance is not upheld.

Second Grievance: Evaluation of Medicinal products requires an enhanced evaluation

- The Appellant submits that given the sensitive nature of the product—which is used in complex abdominal surgery and remains permanently implanted in the body—an enhanced evaluation should have been conducted. The Appellant cites the Court of Appeal decision in *V.J. Salomone Pharma Limited vs Direttur tad-Dipartiment tal-Kuntratti et.*, which held that in matters of a delicate nature involving the supply of medicinal products to patients who have undergone serious operations, the Board should proceed with greater caution.

- This Board has carefully considered this submission and the testimony of the evaluators. Unlike Case No. 2086, where the Board identified significant procedural flaws including the failure of the Evaluation Committee to meet, improper sequencing of the evaluation process, and reliance on a single evaluator, the present case demonstrates a properly constituted Evaluation Committee.

- The evaluation in the present case was conducted by a three-member Evaluation Committee comprising qualified medical professionals with specialized expertise in the relevant surgical field. The Committee was chaired by Mr. Hristo Ivanov Hristov, with evaluators Dr Rachel Abela (Consultant), Mr Charles Cini (Consultant in Colorectal and Minimally Invasive Surgery), and Mr Matthew Sammut (Consultant Surgeon).

[8] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) defines compatibility. *'Compatibility' is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to: (a) perform without losing or compromising the ability to perform as intended, and/or (b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or (c) be used together without conflict/interference or adverse reaction.*

- The testimony of Mr. Charles Cini established that the Committee reviewed all documentation submitted online, examined samples from bidders, and conducted physical testing of the products with the HEM-O-LOK endoscopic applier. This constitutes an appropriately thorough evaluation process for a medical device of this nature.

- The Board finds no evidence that the evaluation was conducted in a manner inconsistent with the requirements for medical products or that the Committee failed to exercise appropriate caution. The Appellant has failed to identify specific deficiencies in the evaluation methodology beyond general assertions that an "enhanced" evaluation was required.

- Accordingly, this grievance is not upheld.

Third Grievance: Offer by recommended bidder is non-compliant

- The Appellant submits that the technical offer submitted by the Recommended Bidder is incomplete and therefore non-compliant, as it failed to complete all required fields in Part 1 of the Technical Offer Form. This additional grievance was authorised by the Board during the first hearing on 25th September 2025, following testimony by evaluator Mr Charles Cini that revealed information not previously available to the Appellant.

- The Technical Offer Form explicitly states: *"Bidders are to complete all the details requested in PART 1 of this document AND the applicable section/s from PART 2 of this document*" and further provides: "*Tenderers that fail to complete and upload the requested information will be deemed as non-compliant and will not be considered further for final adjudication*".

- The testimony of Mr Charles Cini established that in relation to Article 2.8 of the Technical Offer Form (and as can be confirmed by the Board), the Recommended Bidder completed the form as follows:

    1. Confirmation that the model offered complied with requirements: Yes
    2. Details of the offer's specifications for the requisite: Refer to Doc 1-20
    3. Reference in the technical literature: Blank

- The Contracting Authority and Department of Contracts contend that the blank field was not mandatory because it stated, "if applicable" and that the requested information was provided elsewhere in the submission.

- This Board must consider the applicable legal framework governing the rectification and clarification of tender submissions. Clause 16.3 of the General Rules Governing Tenders states that: "*Submissions which have qualified under Part 2 shall have their technical offer evaluated to ensure compliance with Clause 5(C) of the Instructions to Tenderers. In order to be considered for this Evaluation, tenderers must submit a completed Technical Offer. Literature may also be requested with the technical offer so that the Evaluation Committee will corroborate the technical compliance of the offers*."

- The Board notes the classification system established in the tender documentation:
  - <u>Note 1.</u> *Tenderers will be requested to clarify/rectify, within five (5) working days from notification, the tender guarantee only in the following four circumstances: incorrect validity date, and/or incorrect value, and/or incorrect addressee and incorrect name of the bidder. Rectification in respect of the Tender Guarantee (Bid Bond) is free of charge. (currently Bid Bonds are not applicable)*
  - <u>Note 2.</u> *Tenderers will be requested to either clarify/rectify any incorrect and/or incomplete documentation, and/or submit any missing documents within five (5) working days from notification.*
  - <u>Note 3.</u> *No rectifications shall be allowed. Only clarifications on the submitted information may be requested. Tenderers will be requested to clarify the submitted information within five (5) working days from notification. Requests for Clarifications and/or Rectifications concerning a previous request dealing with the same shortcoming shall not be entertained The Technical Offer Form was classified under Note 3, which permits clarifications but not rectifications.*

- The distinction between rectification and clarification is critical and has been addressed by the Court of Appeal. In the judgment *Signal 8 Security Services Malta Limited v. Environment and Resources Authority* decided on 3rd September 2024, the Court stated:

  "Kemm mid-dokument tas-sejha nnifsu (ara Notes to Clause 5 Spagna 5 tad-dokument tas-sejha), kif ukoll anke fil-procurement policy li qieghda tant tishaq dwarha l-appellanti (f'pagna 4 ta' Procurement Policy Note #40), nsibu mnizzel li, fil-kaz ta' dawk ir-rekwiziti li skont id-dokumenti tal-akkwist jaqghu fil-kategorija ta' Note 3, l-awtorità kontraenti ma tistax titlob rettifiki, u [o]nly clarifications on the submitted information may be requested.

  Ghar-ragunijiet li digà nghataw, il-Qorti jidhrilha li f'dan il-kaz, il-procedura ta' kjarifika ma setghet tbiddel xejn minn-nuqqas tal-appellanti li tressaq ritratt jew xbieha tas-security clip fuq I-ingravajjet kif mitlub fid-dokumenti tal-akkwist.

  Fi kliem iehor, bil-kjarifika jew minghajrha, fl-offerta teknika tal-appellanti xorta wahda ma kienx sejjer ikun hemm ritratt jew xbieha tas-security clip mitluba, u ghalhekk, skont ir-regoli tas-sejha, il-kumitat tal-evalwazzjoni ma setax jaghtiha I-punti ghall-kriterju B5(a), bil-konsegwenza li l-iskwalifika tal-offerta taghha kienet inevitabbli."

- This judgment establishes that when information falls under Note 3 classification, clarification procedures cannot remedy the complete absence of required information from the technical offer. The Court emphasised (in line with *Procurement Policy Note #40)* that only clarifications on submitted information may be requested, and clarification cannot substitute for missing mandatory content.

- Similarly, the Court of Appeal in the judgment *Servizzi Malta vs Direttur tal-Kuntratti* decided on 15th July 2018 stated that " *ic-cirkostanzi fejn il-principju ta proporzionalità ma jhallix li offerta titwarrab minhabba irregolarità huma "limitati" u "eccezzjonali*".

- The Board opines that the present case does not fall within the limited and exceptional circumstances where the principle of proportionality would prevent rejection of an offer due to irregularity. The technical offer form is a mandatory document that forms the basis for evaluation. The requirement to complete all fields is explicit and unambiguous.

- The Contracting Authority's argument that the information was provided elsewhere in the submission violates the principle of self-limitation. The Contracting Authority established the structure and requirements of the technical offer form and cannot subsequently accept compliance through alternative means not contemplated in the tender documentation.

- The argument that "*if applicable*" renders the field optional is rejected by this Board. The "*if applicable*" notation relates to whether bidders have technical literature to reference, not whether the field itself must be completed. If no literature reference was applicable, the appropriate response would have been to indicate "N/A" or "*Not Applicable,"* not to leave the field blank. The complete omission suggests the form was not fully completed as required.

- This Board concludes that the Recommended Bidder's technical offer form was incomplete, falling under Note 3 classification where rectification is not permissible. The Evaluation Committee erred in proceeding to evaluate an incomplete technical offer in breach of the tender's own terms and the principle of self-limitation.

Accordingly, this grievance is upheld.

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 related to the first grievance '*Product offered by recommended bidder is not "fully compatible"*'

b) Does not Uphold the Appellant's Letter of Objection and contentions related to the second grievance '*Evaluation of Medicinal products requires an enhanced evaluation*.

c) Upholds the Appellant's Letter of Objection and contentions related to the additional (third grievance) '*Offer by recommended bidder is non-compliant'*

d) Revokes the recommendation of award made in favour of the Recommended Bidder;

e) Directs that the evaluation be reviewed, orders the reintegration of the Appellant's bid in the re-evaluation process;

f) Directs that bidders be requested to extend the validity period of their respective bids, if required;

g) Directs that the deposit paid by Appellant to be **refunded in full**.

Dr Vincent Micallef **Chairman**	**Dr Ing. Damien Gatt** **Member**	**Mr Lawrence Ancilleri** **Member**