PUBLIC CONTRACTS REVIEW BOARD

Case No 2079 – CfT020-3165/24 CPSU5231/24 – Supplies - Tender for the Supply of Various Items for Stoma 70mm

24th February 2025

The Board,

Having noted the letter of objection filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja acting for and on behalf of **Krypton Chemists Limited**, (hereinafter referred to as the appellant) filed on the 31st October, 2024;

Having also noted the reasoned letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for and on behalf the **Central Procurement and Supplies Unit** (C.P.S.U) (hereinafter referred to as the Contracting Authority) on the 7th November, 2024;

Having also noted the letter of reply filed by Dr Keith Borg acting for and on behalf of **ATG Company Limited** (hereinafter referred to as the Recommended Bidder) filed on the 11th November, 2024;

Having heard and evaluated the testimony of the witness Ms Bernice Gauci (Chairperson of CPSU's TEC) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Ms Maria Curmi (Tender Coordinator of CPSU) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Ms Josianne Rapa (Evaluator of CPSU) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Ms Renata Batas (online witness) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Ms Pina Erklavec (online witness) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Mr Matthew Arrigo (Representative of Krypton Chemists Limited) as summoned by Dr Clement Mifsud Bonnici acting for Krypton Chemists Limited;

Having heard and evaluated the testimony of the witness Dr Louise Calleja (online witness) as summoned by Dr Alexia J Farrugia Zrinzo acting for CPSU;

Having heard and evaluated the testimony of the witness Profs. Charmaine Gauci (online witness) as summoned by Dr Alexia J Farrugia Zrinzo acting for 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 18th February, 2025 hereunder-reproduced.

Minutes

Case 2079 –CfT020-3165/24 - CPSU 5231/24 – Supplies - Tender for the Supply of various items for Stoma 70mm

The tender was published on the 16th February 2024 and the closing date of the call for tenders was the 8th March 2024.

The estimated value of this tender, excluding VAT, was € 117,996.

On the 31st October 2024 Krypton Chemists Ltd filed an appeal against the decision of the Central Procurement and Supplies Unit to disqualify their offer on the grounds that it was technically not compliant.

A deposit of € 590 was paid.
There were five bids.

On the 18th 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 – Krypton Chemists Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Dr Calvin Calleja	Legal Representative
Dr Krista Refalo	Legal Representative
Mr Matthew Arrigo	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Bernice Gauci	Chairperson of the Evaluation Committee
Ms Josianne Rapa	Evaluator
Ms Maria Curmi	Representative

Recommended Bidder - ATG Company Ltd

Dr Keith Borg	Legal Representative

Dr Vincent Micallef Vice-Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Clement Mifsud Bonnici stated that this appeal is based on the letter of rejection of appellant's bid and on the reason given for the rejection, with a third grievance based on the written submissions. Appellant is not requesting cancellation of the tender and the appeal shall be concentrating on the first two grievances.

The Public Procurement Regulations (PPRs), inherited via the EU Directive, have as a main point cross border trading which applies to all EU countries and which is central to today's appeal.

Dr Alexia Farrugia Zrinzo said that the basis of the Contracting Authority's decision will be proven through the testimony of witnesses and the written submissions.

Dr Keith Borg Legal Representative for ATG Co Ltd said that at this stage the preferred bidder relies on the written submissions and will follow the process as it evolves.

Ms Bernice Gauci (476186M) called to testify by the appellant stated on oath that she was appointed Chairperson of the Tender Evaluation Committee (TEC) after the evaluation had been finalised and had taken no part in the process.

Ms Maria Curmi (288592M) called to testify by the appellant stated on oath that she was the tender co-ordinator and Secretary of the TEC. There had been no evaluation meetings and the final report was prepared from the report uploaded on the ePPS.

Ms Josianne Rapa (413503L) called to testify by the appellant stated on oath that she was the sole evaluator on this tender and no technical advisors had been appointed. She had previous evaluation experience but was not familiar with the General Rules Governing Tenders. Witness stated that the appellant was disqualified at the second stage of the evaluation but subsequently indicated that she is not aware at what stage disqualification happened as she had merely followed the directions of the Malta Medicines Authority (MMA) decisions.

The reason for rejection had been drafted by the witness and refers to products listed as items 1 and 2 in the tender. The reason witness referred to 'product' in the rejection letter is that the rest of the items in the list could not be used without items 1 and 2 and hence she considered the package as one product. The incident reports referred to in the Authority's reply were received from nurses administering Stoma including ones prepared by the witness herself. She was aware of these incident reports prior to the evaluation. Witness was aware that the complaints were on products with a different code number to that in the tender but the wafer used was the same. As a nurse, she was fully aware of the seriousness of the incidents recorded and the problems caused and she could not approve the product once she was aware that it was faulty. Witness stated that she was not aware of any blacklisting on either the appellant or Lentismed.

In reply to questions from Dr Farrugia Zrinzo, witness said that patients had suffered a skin reaction from the base plate of the product and explained that Stoma consists of several items which all have to be used as one appliance.

Ms Renata Batas (ID 006092234) called to testify online by the appellant stated on oath that she is a registered nurse and a Stoma therapist with experience of stomach diseases and a Masters degree. Her experience of Lentell products are good, easy to use and meet patients' satisfaction. She has not known of any incident reports relating to Stoma products - there were some problems with leakages but these were patients related rather than product problems and had always been resolved.

In reply to questions from Dr Farrugia Zrinzo, witness said that she had personally used Lentismed products on patients. She had been contacted in the last day or two through e-mail seeking information requesting her to justify the quality of the product; she had never heard of Krypton prior to this.

Ms Pina Erklavec (ID 004660026) called to testify online by the appellant stated on oath that she is a graduate in Occupational Therapy and since 2016 she has a managerial role at the Lentismed company in Slovenia producing Stoma products. Her company has corroborated with Krypton as their distributor since 2021 and had provided certification and information for the tender bid. She was aware of the five product codes offered in the tender. Apart from being located in three countries Lentismed has representation and distribution arrangements in several EU countries. Incident reports had only been received from Malta but they referred to codes different to the ones offered in the tender. These particular product codes referred to in the tender were supplied to Krypton as recently as January 2024.

Questioned by Dr Farrugia Zrinzo, witness said that she was part of the team that had investigated the reported incidents.

Mr Matthew Arrigo (188094M) called to testify by the appellant stated on oath that he is a Director of Krypton Chemists Ltd and had prepared the tender proposal. His company had been exclusive distributors of Lentismed products in Malta since 2020. He confirmed that the company had received incident reports in October 2023 on product code 201117 AB which product was not being offered in this tender. Stoma products had been supplied by Krypton since 2021 or 2022 and the incident reports were received in 2023. The last order received from the Contracting Authority for Lentismed products was in 2025 following several confirmed orders as listed in the exhibit tabled in the submissions.

Prof Charmaine Gauci (22267M) called to testify online by the Authority stated on oath that her role is that of regulator of medicinal products and medical devices and she is not involved in procurement. Her role is to protect public health and if there are any issues on medical devices she ensures that the necessary action is taken. The normal procedure when any reports of adverse events on medical devices are received is to refer them to the advisory committee of the MMA which investigates and issues reports and eventually recommendations to the CEO of the Authority. Eventually these are passed to the witness in her role as Superintendent of Public Health (SPH). If the issue is one of patients' safety or of adverse events to the quality of life of patients then a recommendation is made to the CPSU to quarantine the suspect product and seek alternatives.

Asked specifically about the Lentismed product query, Prof Gauci said that she was only alerted the previous day regarding the tender so she had little time to find out details and further details of any complaints or recommendations can be provided by others.

At this stage, Dr Mifsud Bonnici said that he will object and will not accept the introduction of last minute documents.

Dr Farrugia Zrinzo said that it is important that the Board hears the testimonies of the public health department as the Authority requested these witnesses to testify quite some time before this hearing.

The Chairman directed that the testimony of Prof Gauci be suspended to enable the necessary documents to be traced and to be made available to the Board.

Dr Louise Grech (506379M) called to testify online by the Authority stated on oath that she is the Director Medical Devices at the MMA and her role is to carry out clinical investigations, technical work and application of regulations concerning medical devices and to investigate incident reports. The advisory committee which comprises representatives of various medical stakeholders considers reports and makes recommendations which eventually are passed on to the SPH. Questions on Lentismed Stoma bags incidence reports should be directed, according to the existing structure, to the chairperson of the advisory committee or the CEO of the MMA. The structure must be observed.

There was at this stage a discussion between the Board and the lawyers for all parties regarding the need to hear further witnesses. Dr Grech was advised that her testimony was being suspended but she might be recalled to testify further.

Prof Gauci was recalled to resume her testimony. She tabled a thread of e-mails (DOC 1) between officials in the Health Department covering correspondence from 2023 regarding incident reports on Lentell Stoma products. Complaints were that flanges were becoming dislodged especially at night time with skin irritations and flare ups including bleeding and bags not closing properly. The complaints were sent to the advisory committee were incidents were evaluated and investigated followed by a recommendation sent to the witness who concurred that the product should be quarantined and alternative product used. The decision was finally passed on to the CPSU.

In reply to questions from Dr Mifsud Bonnici, witness was referred to what the title of the tender covered but replied that it was not her role to view tenders and she was not consulted either on the specifications of the tender nor the evaluation. It is the advisory committee that handles investigations with herself finally confirming the recommendation or otherwise – recommendations are not binding. Referred to the 11th January 2024 e-mail, Prof Gauci stated that she is not aware if the CEO had given an actual approval but that is the normal procedure.

The product codes in question were not known to witness as she relies on technical people for evaluations and she is given summaries of incident reports. She does not take these reports at face value as she knows they have been processed by highly experienced and competent technical people whom she relies on. E-mails are not her only source of information as there are ongoing discussions on matters such as these and the subject would have already been discussed although she does not herself see the reports and the evaluations. It is the CPSU's responsibility as procurer to advise suppliers if any problems are encountered on a product.

In reply to a question from Dr Farrugia Zrinzo, witness said that as SPH she expected the CPSU to follow a recommendation to quarantine a product and to seek alternative products.

In reply to a further question from Dr Mifsud Bonnici, witness said that if a recommendation is not followed by the CPSU then alternative measures have to be considered. In this instance, the recommendation was followed.

This concluded the testimonies.

Dr Calvin Calleja Legal Representative for the appellant said that the point of this appeal is the reason for rejection given in the letter of exclusion. It is the decision of the TEC that matters and the reason given raised more questions than answers. Why does the TEC refer to past problems when dealing with a new product? Ms Rapa in her testimony stated that she did not rely on blacklisting to exclude – therefore this could not have been the reason. The decision was therefore arbitrary and unfounded and certainly not in line with the PPRs or the General Rules. Appellant was told that the product was dealt with as a single unit but this was not stated in the rejection letter. Two witnesses testified that Lentismed incidents recorded were on a different and distinct product code (201117AB) totally different to the product in question. To justify the decision to exclude appellant the TEC relied on hearsay hence flagrantly ignoring the principle of self-limitation. Reference was made to the *Nexans France* case (T415/10) emphasising the point of equal treatment. It is totally not proportional to disqualify not just a product but a whole international firm.

According to the testimony of Dr Batas, continued Dr Calleja, a person who had over 30 years' experience in these matters, she has never had any complaints with this product. In 2016, the PCRB heard an exactly similar case number 1136, involving the same parties as those here today, on microporous dressings were one party was excluded as CPSU had experience of incidence report. The then Board noted that although the brand was the same the requirements were different.

Dr Mifsud Bonnici stated that the basis of self-limitation, transparency and equal treatment are fine principles but halfway through this evaluation a new point of disqualification was introduced – hence the decision must be quashed. The important point is that witness divulged that before starting her evaluation she was already aware of reports of incidences – a statement that sails close to the wind of a conflict of interest. The e-mail from the SPH is very generic with no reference to product or reason for rejection and therefore totally irrelevant. The Board has heard the usual mantra of patients' safety but no reference to product or product code; however, the principles of procurement are supreme even over patients' safety.

Dr Borg said that the point of this hearing is to find out the truth. Witness Ms Rapa mentioned the severe suffering undergone by the patient and by his nurse which highlights patient's safety. Two Civil Court decisions were cited:

Case 1665/2020 (11/12/2020) *Segretarju Permanenti Ministeru tas-Sahha vs MUMN*
Case 1400/2021 (11/10/2021) *Direttur Generali Off. Perm. Ministeru tas-Sahha vs MUMN*

The cardinal point made in both these cases, said Dr Borg, was that if the exercise of a right puts at risk, or at a possible risk, the life of a patient that right should not seek comfort from our judicial organs – hence patients' safety should not be subsidiary to the law – as claimed by the appellant. The product has been described as operating as a whole appliance and the parts cannot be operated solely; if one part fails the others do not work.

Dr Farrugia Zrinzo stated that Ms Rapa followed the recommendation of the SPH. We heard the SPH in turn explain how decisions are reached. The SPH recommended to the CPSU that a product is not procured and therefore, the CPSU followed that advice which is in the interest of patients and public health. In the case quoted on microporous dressings there was only one report – in this case there several incidents were reported including one involving Ms Rapa who witnessed the effect of the incidence on a patient. In DOC 1 there is a reference to 'three more reports' which clearly indicates that there were many reports and the consequences thereof. These are vulnerable patients who do not need these problems and one cannot hide behind the PPRs and the letter of exclusion to make a case. How much further one has to go than to state product 'is not up to standard'. The CPSU followed the recommendation of the SPH nand followed the decision of the TEC.

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

End of Minutes.

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Hereby resolves:

The Board refers to the minutes of the Board sitting of the 18th February, 2025.

Having noted the objection filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja for and on behalf of Krypton Chemists Limited (hereinafter referred to as the Appellant) on 31st October, 2024, refers to the claims made by the same Appellant with regard to the tender of reference CfT020-3165/24 CPSU5231/24 listed as case No. 2079 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Clement Mifsud Bonnici and Dr Calvin Calleja
Appearing for the Contracting Authority:	Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri
Appearing for the Recommended Bidder	Dr Keith Borg

Whereby, the Appellant contends that:

The Tender was published by the Contracting Authority on 16 February 2024 with a closing date of 8 March 2024. Its purpose was the procurement of a year's supply of stoma items with a collective estimated procurement value of €117,996:

- Item 1 (Skin barriers (body wafers) with tape border) - 11,000 units
- Item 2 (Skin barriers (body wafers) without tape border) - 17,000 units
- Item 3 (Closed ostomy pouches) - 49,000 units
- Item 4 (Drainable ostomy pouches) - 16,000 units
- Item 5 (Urostomy pouches) - 3,000 units

By the closing date, 5 tenders had been received. The Appellant's offer ranked second with a price of €120,533.40 while the Recommended Bidder's offer ranked third with a price of €126,910.

On 22 October 2024, the Appellant received a rejection letter ("Document KCL1") where according to the stated reason for rejection: *"Multiple incident reports of skin irritations were submitted; Thus, this product is not acceptable"*.

The Appellant is aggrieved by the Contracting Authority's decision and shall humbly demand the Public Contracts Review Board (the "PCRB") to overturn the decision, reintegrate the Appellant's offer in the

tender process, and order the re-evaluation of the bids by the evaluation committee.

FIRST GROUND OF APPEAL: THE REASON FOR REJECTION IS UNFOUNDED

The Appellant humbly submits that the reason for rejection is unfounded, having no basis in either fact or law.

1. The Contracting Authority claims that the Appellant's product is not acceptable because of a number of incident reports that were allegedly submitted regarding skin irritations.
2. The Appellant understands that the allegation being made in the letter of rejection is that these incident reports were submitted in relation to the *"product"* offered by the Appellant.

Firstly, the Tender asks for 5 different stoma products, all of which are listed in the technical offer form. The Appellant humbly submits that it has not received any incident reports in relation to the product codes submitted in its technical offer. The same product codes have been available on the market throughout the year 2024 and the contractor has no record of any observations, complaints or incident reports. The below codes referred were distributed at Mater Dei Hospital, without any reported issues.

The letter of rejection does not specify the product codes in relation to which the incident reports have been allegedly received. This is the minimum information which is required in a rejection letter.

The Appellant submits that the Contracting Authority has fallen foul of its obligation to provide the reasons for rejection and to enable the Appellant to exercise its right to a rapid and effective remedy.

THE SECOND GROUND OF APPEAL: THE CONTRACTING AUTHORITY HAS CHANGED THE REASON FOR REJECTION EX POST FACTO

Upon receiving the letter of rejection, the Appellant wrote to the Contracting Authority to explain that it has no record of any incident reports relating to the product codes in the technical offer form. It requested the Contracting Authority to clarify the matter, including by reference to supporting documentation.

The Contracting Authority replied on 28 October 2024 stating that: *"you have been informed repetitively of incident reports related to the brand Lentismed. For this reason, the evaluation committee stands by its decision"*.

The Appellant acknowledges that in the past, it has received incident reports in relation to a single product code from the Lentell range from a separate procurement cycle which is in no way related to the Tender in subject.

This clarification response from the Contracting Authority did not provide a record or trail of any incident reports on the product codes enclosed in the Appellant's technical offer form.

Instead, it proceeds to justify its decision by referring to the brand of the product codes enclosed in the Appellant's technical offer form, which was not disclosed in the original reason for rejection.

Secondly, the allegation that incident reports have been submitted in relation to a brand of products is not a valid reason for rejection. The Appellant's bid comprises unique product codes all of which are compliant with the technical specifications and have been previously delivered to the Contracting Authority as recently as April 2024. The Appellant reiterates that no observations, complaints or incident reports have ever been received for the product codes in the technical offer. Nor have observations, complaints, or incident reports resulted from the Appellant's continuous market surveillance exercises which it is obliged to conduct.

Furthermore, the Tender does not prohibit the participation of contractors who have received incident reports in relation to a separate procurement cycle which is in no way related to the Tender in subject.

The Appellant submits that if this were the case, the technical specification would be discriminatory, anti-competitive, and disproportionate, violating all the principles underpinning public procurement in Malta and exposing the tender to the possibility of an application for a pre-contractual remedy.

Therefore, the Appellant humbly demands the PCRB to declare the decision of the Contracting Authority to be unfounded in fact and in law and to revoke the said decision.

THIRD GROUND OF APPEAL: THE CONTRACTING AUTHORITY'S CONDUCT BREACHES THE PRINCIPLE OF GOOD ADMINISTRATIVE BEHAVIOUR

The evaluation took 228 days to conclude which translates into an additional 138 days beyond the 90-day validity period of tenders. According to Rule 8.1 of the General Rules Governing Tenders, tenderers are required to maintain the validity of their tenders for a period of 90 days after the closing date.

It is customary for evaluations to be concluded within the validity period of tenders. Failure to do so requires the Contracting Authority to reach out to the bidders to request an extension to the tender validity.

The Contracting Authority gave no explanation to the bidders for this delay and why a tender with a closing date in March 2024 has been adjudicated in October 2024. Nor did the Contracting Authority request the Appellant to extend the validity of its bid.

The Appellant submits that this unjustified delay in the adjudication of the Tender falls short of the standard of good administrative behaviour which contracting authorities are bound to implement.

Therefore, the Appellant humbly demands the PCRB to declare the decision of the Contracting Authority to be in breach of the applicable procedure and to revoke the said decision.

This Board also noted the **Contracting Authority's** Reasoned Letter of Reply filed on 7th November 2024 and its verbal submission during the hearing held on the 18th February 2025, in that:

On the First Ground of Appeal

CPSU submits that the objector is well aware of the situation and is using this objection opportunity to achieve other ends instead of using the proper legal channels at law;

A number of incident reports were indeed received by the Medicines Authority and the Licensing Authority on the stoma items produced by the brand marketed by the objector;

The objector is attempting however to use the fact that the incident reports were on other sizes and not on the sizes requested in this call for tenders, in its favor(sic). Respectfully, the contracting authority disagrees as what applies for a size is still applicable for the other sizes produced by the same manufacturer;

Moreover, the decision not to procure the product offered by the objector from the manufacturer 'Lentismed' irrespective of the size, is backed up by a decision of the Superintendent of Public Health, in the interest of the patients;

The Superintendent of Public Health as established in the Public Health Act, Chapter 465 of the Laws of Malta is responsible for public health in Malta! and can "give any order that he may deem necessary"

The decision of the evaluation committee is therefore well founded both in fact and at law, and thus this first ground of appeal ought to be rejected.

On the Second Ground of Appeal

The objector in its second grievance alleges that the contracting authority has changed its reason for rejection *ex post facto* and attempts to substantiate this argument by citing the email sent by the tender

coordinator on the 28th of October 2024. The fact that the email of the 24 of October is being cited is a reason in itself for this ground of appeal not to be upheld, because this same email state expressly that *"the evaluation committee stands by its decision"*.

As will be further explained during the sitting the reason for rejection as(sic) always been one and the same and there was no ex-post facto change in any decision;

In light of the above this second ground of appeal ought to be rejected as well;

On the Third Ground of Appeal

The appellant in this third ground of appeal states that the contracting authority did not follow good administrative behavior(sic), because it did not issue a clarification request requesting bidders to confirm their offer after the 90 days validity period established in clause 8.1 of the General Rules Governing Tenders;

Whilst it may be true that such clarification was not requested, the fact that this objection was presented in the first place by the objector, especially when looking at the first 2 grounds of appeal, shows that the objector is still interested in the tender!;

Sub-clause 8.1 of the General Rules Governing Tenders is an obligation on the economic operator, rather than an obligation on the contracting authority, in fact clause 8.1 is the only part of clause 8 which imposes a *sine qua non* obligation using the word shall, imposing an obligation on the bidder;

All other parts of this clause use the word may, clearly showing a discretion, such as sub-clause 8.2 which states that *"Head of Contracting Authority may consider cancelling the tender"* and sub-clause 8.4 states *"Following the further extension by eight (8) weeks, the non-conclusion of the evaluation process may lead to the cancellation of the tender.*"

Even the clause which mentions the extension, does not impose any *sine qua non* obligation on the contracting authority:

In exceptional circumstances, the Central Government Authority/Ministerial Procurement Unit/Contracting Authority may request that tenderers extend the validity of tenders, without the need to extend the validity of the Tender Guarantee (Bid Bond) (as being referred to in Article 9.2 of these General Rules), for two further periods of four (4) weeks each. Such requests and the responses to them must be made in writing. A tenderer may refuse to comply with such a request without forfeiting his tender guarantee

(Bid Bond). However, his/her tender will no longer be considered for award. If the tenderer decides to accede to the extension, he/she may not modify his/her tender.

CPSU submits that the principle *ubi lex voluit dixit, ubi noluit tacuit* applies as well in this circumstance and if the drafters of the General Rules Governing Tenders wanted the ipso facto cancellation of the tender upon expiration of the validity of tenders, it would have expressly stated so;

Instead, the drafters mention cancellation as a discretion, and do not refer to any other remedy. From a reading of the requests of the objector it is clear and evident that the objector is not seeking the cancellation of the tender but rather a re-evaluation of this same tender. The scope of this third grievance is thus very unclear, and for all these reasons, should be rejected.

This Board also noted the **Recommended Bidder's** Reasoned Letter of Reply filed on 11th November 2024 and its verbal submission during the hearing held on the 18th February 2025, in that:

The first ground of appeal

The reason for the rejection of Appellant is not unfounded in that indeed, the product offered by the Appellant, as also submitted by the Contracting Authority in its submission of the 7 November 2024, is unacceptable.

Respectfully, the fact, if true, that the Appellant *"has not received any incident reports"* and *"has no record of any observations, complaints or incident reports"* does not mean that the said repeated incident reports were not duly registered and received.

It is also untrue that the Contracting Authority has fallen foul of its obligation to provide a reasoned refusal for rejection. The rejection letter dated 22 October, 2024 is indeed sufficiently reasoned and, as will be submitted hereunder, rooted in fact.

The second ground of appeal

The Recommended Bidder here draws this Board's attention to the contradiction in Appellant's arguments of the alleged fact. In its first ground of appeal, the Appellant starkly states that it "*has not received any incident reports"* and "*has no record of any observations, complaints or incident reports"*. In its second ground of appeal, the Appellant now states that it "*acknowledges that in the past, it has received incident reports in relation to a single product code from the Lentell range"*.

In view of this admission, the Contracting Authority needed not provide the Appellant with a record on the repeated incident reports relating to the product which the Appellant offered. The Contracting Authority has therefore not changed, as alleged by the Appellant, the reason for rejection *ex post facto*.

Repeated incident reports submitted in relation to the brand offered by the Appellant do indeed constitute a valid reason for rejection. Appellant's assertion that the Tender does not prohibit the participation of contractors who have received incident reports due to an unacceptable product is appalling, particularly in the health sector.

The third ground of appeal

The Recommended Bidder submits that the Contracting Authority did not breach the principle of good administrative behaviour.

It is sufficient to draw this Board's attention here that this grievance is, as perfectly submitted by the Contracting Authority in its submission of the 7 November 2024, not based on any provision of law or regulation.

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. Given that the appellant's legal counsel declared during the hearing that the appeal *per se'* should be concentrated on the first two grievances, the Board, albeit it will be taking cognizance of all the issues raised in the written pleadings, will be focusing on the grievances emphasised by same appellant.

The Public Contracts Review Board (the "Board") has carefully reviewed the appeal at hand, which pertains to the rejection of a tender for the supply of various items for Stoma, specifically the flaws in the evaluation process conducted by the Technical Evaluation Committee (TEC). After considering the relevant documents, evidence presented, and the established procurement policies, the Board concludes that there were multiple deficiencies in the evaluation process that warrant a review of the decision.

Evaluation by a Single Evaluator

The most fundamental flaw identified in this case is the fact that the tender was evaluated by only one evaluator. As highlighted in an online document entitled *"Standard Operating Procedures (SoP) Guidelines for Tender Evaluation Committees (TEC) Version 1.1 Department of Contracts"*, it is clearly stated that a TEC should consist of a minimum of three evaluators or any odd number, unless otherwise approved by the Director

of Contracts. This procedural requirement is not merely advisory but forms a part of the established principles for tender evaluation, as also corroborated by the Public Procurement Policy Notes on the Department of Contracts website, particularly PPN 40.

The importance of multiple evaluators lies in the collective and balanced judgment they bring to the process, reducing the risk of bias and ensuring a more objective evaluation of tenders. By evaluating the tender in isolation, the process was inherently flawed, and the decision made by a single evaluator cannot be considered in line with best practices. It is imperative that these guidelines are in place and be adhered to rigorously to ensure transparency, fairness, and consistency in public procurement.

Flawed Evaluation Process and Hearsay Evidence

The sole evaluator in this case testified under oath that no technical advisors had been appointed, and that she was not familiar with the General Rules Governing Tenders. More concerning, she stated that she had followed the directions of the Malta Medicines Authority (MMA) in making her evaluation. This raises significant issues, particularly in the realm of evidence and objectivity. The reliance on the MMA's decisions, without independent verification or technical expertise, creates a situation where the evaluation is based on hearsay rather than solid, first-hand evidence regarding the quality and suitability of the products.

The Board notes that the MMA's instructions, while important in ensuring the safety of patients, should not override the technical evaluation process which must be independent and objective. The evaluator's lack of familiarity with the rules governing tenders further undermines the objectivity of the decision. The evaluator's testimony, which relied on the directions of the MMA rather than her own technical judgment, constitutes a serious procedural flaw that the Board cannot overlook.

Prejudiced Evaluation

The sole evaluator, as a nurse with prior experience of incidents related to Stoma products, acknowledged that she was aware of various incident reports, **some of which she had prepared herself**. While her concern for patient safety is commendable, it is, still, the opinion of this Board that her personal experience with the product created a potential conflict of interest. The Board is particularly concerned with the fact that, as the only evaluator, her personal biases may have influenced the rejection of the tendered products. This raises issues of transparency and fairness, as the evaluator's decision was not made solely based on the technical merits of the product but was also influenced by her prior experience and subjective perceptions.

Furthermore, the evaluator's awareness of specific incident reports that related to products with a different code number than those in the tender further underscores the flaws in the evaluation. The decision to reject the tender based on these reports, without verifying the relevance of the incidents or considering the correct product code numbers, introduces a significant error in judgment.

Rejection Based on Product Brand and Inaccurate Disqualification

The appellant correctly points out that rejecting the tender based solely on the product brand is not justifiable. Each product has a distinct code number, and the evaluator's decision to reject the tender for a product with a different code number from the one in the tender constitutes, in the opinion of this Board, an error. The evaluation should have been based on the specific product code presented in the tender and the technical specifications outlined therein. A general rejection based on brand, without considering the exact product code and the tender requirements, is not consistent with the principles of public procurement.

Moreover, the evaluator's testimony that she was unaware of any blacklisting of either the appellant or Lentismed further suggests that the rejection was based on improper or incomplete information. The absence of a valid, fact-based rationale for disqualification is a serious oversight.

Conclusion:

It is of paramount importance to reiterate time and again, *ad nauseam* indeed, the emphasis of patients' safety in public procurement matters. That said and despite the Board's full cognizance of the need to protect patients' interest, the TEC's decision is so flawed that, at this juncture, it is overridden by other considerations.

Based on the above findings, the Board concludes that the evaluation process in this case was fundamentally flawed on several grounds. The failure to adhere to the minimum requirements for the composition of the TEC, the reliance on hearsay evidence, the potential conflict of interest introduced by the evaluator's personal experiences, and the improper rejection of the tender based on inadequate or incorrect information all point to a failure to comply with established procurement procedures

The Board, therefore, directs that the evaluation be reviewed and that a proper evaluation process be conducted. This review should include the appointment of an appropriately constituted TEC, with at least three evaluators, to ensure an impartial and transparent process.

Therefore, this Board upholds Appellant's grievances.

The Board,

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

a. To uphold Appellant's Letter of Objection and contentions;
b. Declares that the reason stated in the Appellant's letter of rejection is unfounded in fact and in law and revokes it;
c. Revokes the recommendation of award made in favour of the Recommended Bidder;
d. Directs that the evaluation be reviewed and that a proper evaluation process be conducted, orders the reintegration of the Appellant's bid in the re-evaluation process, which re-evaluation shall implement the Board's findings;
e. Directs that this review should include the appointment of an appropriately constituted TEC, with at least three evaluators, to ensure an impartial and transparent process, including requesting bidders to extend the validity period of their respective bid;
f. Directs that the deposit paid by Appellant to be reimbursed.

Dr Vincent Micallef **Chairman**	**Mr Lawrence Ancilleri** **Member**	**Mr Keith Victor Grech** **Member**