

## **PUBLIC CONTRACTS REVIEW BOARD**

### **Case 1989 – CfT020-3432/23 (CPSU5567/23) – Supplies – Tender for the supply of Hypodermic Syringes (5.0ml – 6.0ml)**

**20<sup>th</sup> March 2025**

The Board,

Having noted the letter of objection filed by Dr Robert Galea acting for and on behalf of ProCare Ltd, (hereinafter referred to as the appellant) filed on the 23<sup>rd</sup> February 2024;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 4<sup>th</sup> March 2024;

Having heard and evaluated the testimony of the witness Mr Patrick Ghigo (Member of the Evaluation Committee) as summoned by Dr Robert Galea, acting for and on behalf of ProCare Ltd;

Having heard and evaluated the testimony of the witness Mr Pierre Calleja (Representative of ProCare Ltd) as summoned by Dr Robert Galea, acting for and on behalf of ProCare Ltd;

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 11<sup>th</sup> April 2024, the second hearing held on the 6<sup>th</sup> March 2025, and the third hearing held on the 11<sup>th</sup> March 2025 hereunder-reproduced.

#### **Minutes**

#### **Case 1989 – CfT 020-3432/23 – CPSU 5567/23 – Supplies – Tender for the Supply of Hypodermic Syringes (5.0ml – 6.0ml)**

The tender was issued on the 4<sup>th</sup> April 2023 and the closing date was the 25<sup>th</sup> April 2023

The estimated value of this tender excluding VAT was € 64,815.

On the 23<sup>rd</sup> February 2024 ProCare Ltd filed an appeal against the Central Procurement and Supplies Unit objecting to their disqualification on the grounds that their bid was deemed to be technically non-compliant.

A deposit of € 400 was paid.

There were ten bids.

On the 11<sup>th</sup> April 2024 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Ms Stephanie Scicluna Laiviera as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

**Appellant – ProCare Ltd**

Dr Robert Galea	Legal Representative
Mr Pierre Calleja	Representative

**Contracting Authority – Central Procurement and Supplies Unit**

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Josette Camilleri	Chairperson Evaluation Committee
Mr Patrick Ghigo	Evaluator
Ms Denise Dingli	Representative
Mr James Said	Representative

**Preferred Bidder – Krypton Chemists Ltd**

Invited but did not attend

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

Dr Robert Galea, Legal Representative for ProCare Ltd, referred to the letter from the CPSU regarding the lack of labelling on the samples supplied and doubted if they were referring to the same item as provided by the Appellant. He wished to question witnesses on this point.

Mr Patrick Ghigo (300874M) called to testify by the Appellant stated on oath that he was one of the evaluators in this tender. He demonstrated the box which he claimed contained the syringe samples submitted by ProCare which certainly does not state the name of the manufacturer.

Dr Galea and Appellant intervened to say that this was not the box of samples submitted by ProCare.

The Chairman said that at this stage the Board would wish to see the receipt given by the CPSU on receipt of the sample.

After further cross questioning of the witness, it was established that it was him who had asked for the samples and the one to ultimately receive them. Contrary to what the Appellant claimed, witness said that the Procurement Officer had not indicated that ProCare had previously supplied this product and that it could not be established if any identification marks were used on receipt of samples.

This concluded the testimony.

Dr Galea said that the facts speak for themselves – the chain of custody of the samples was not good. Since the samples produced by the witness had no markings there was no certainty as to their origin or that they came from the Appellant. This product has been previously supplied by ProCare, so why distinguish them from Krypton which were not asked for samples. This same product had already been accepted under a tender decided in PCRB Case 1931. The samples demonstrated by witness did certainly not come from Appellant.

Dr Farrugia Zrinzo on behalf of the CPSU stated that witness had confirmed on oath that the samples shown were exactly as received and one must assume that these came from Appellant and the evaluation had been carried out on the ProCare product. The samples presented by ProCare in PCRB Cases 1916, 1917 and 1918 were not the ones that Appellant felt had been supplied.

Dr Galea said that today's case is different as the box does not even state the name of the manufacturer and is totally blank of any printing.

The Chairman called for a short recess to enable the Board to decide on the submissions made.

On resumption, the Chairman said that the Board had considered the submissions made from which it is clear that the chain of custody of the samples submitted by ProCare Ltd is far from certain and was not made any clearer in the testimony of Mr Ghigo. There is doubt as to what exactly happened once the samples were handed to the reception at the Contracting Authority. The Board has also not had sight of the related receipt issued. Once the tracing of the samples submitted by ProCare is not clear, it is incumbent on this Board to take a decision on the outcome.

This Board, therefore, directs that this appeal is deferred to give the Contracting Authority the opportunity to carry out an internal exercise to establish how the samples submitted by ProCare and those of other economic operators were handled and to present the result of this exercise at the next sitting of this case. During the course of today's sitting, it was mentioned that the evaluators were advised by the Procurement Officer regarding past suppliers of the product subject of this tender. This Procurement Officer is being summoned to attend the next sitting and to testify if necessary.

As agreed between the parties, the Contracting Authority is being granted a term of one month to carry out this exercise and make it available to all parties concerned.

The Chairman thanked the parties and declared the hearing adjourned.

End of first day of hearing

---

## SECOND DAY OF HEARING – 6<sup>th</sup> March 2025

On the 6<sup>th</sup> March 2025 at 10.30 am the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Ing. Damien Gatt and Mr Lawrence Ancilleri as members convened a public hearing to continue considering the appeal following the first hearing held on the 11<sup>th</sup> April 2024

The attendance for this public hearing was as follows:

### **Appellant – ProCare Ltd**

Dr Robert Galea	Legal Representative
Mr Pierre Calleja	Representative
Mr Clive Muscat	Representative

### **Contracting Authority – Central Procurement and Supplies Unit**

Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Josette Camilleri	Chairperson Evaluation Committee
Mr Patrick Ghigo	Evaluator
Mr James Said	Representative

Mr. Kenneth Swain, Chairman of the Public Contracts Review Board, welcomed the parties and explained that Board member Ms. Stephanie Scicluna Laiviera, who had participated in the first sitting, had resigned from the Board. Dr. Ing. Damien Gatt was appointed to replace her for the second sitting. He further noted that Mr. Harry Fenech, the Board Secretary, had retired, and Ms. Amy Borg from the

Board's secretarial pool was brought forward to assume his role for this sitting. The participants expressed their agreement with the current panel and confirmed that they had no objections.

The Chairman then referred to the previous hearing when Mr. Patrick Ghigo, as witness and under oath, was answering questions on the issue of the chain of custody of the sample in question.

The Chairman also emphasized the fact that he had ordered the CPSU, the contracting authority, to present a report to establish the process about the sample, and this to be copied to the appellant who in turn confirmed that he had received it.

Dr. Robert Galea for ProCare Ltd submitted that besides the testimony of Mr. Ghigo, which does not throw any light on the process of the chain of custody, this document, presented on the 21<sup>st</sup> May 2024 before this second sitting, has created a situation where we are back to square one. CPSU were asked to provide a document to explain the chain of custody. This document, besides being unsigned and unconfirmed by anyone, does not explain and describe what happened in the process of the chain of custody in question. It just describes a process which is supposed to happen in all cases when samples are presented to the CPSU; that is: 1. Samples are received by the receptionist at the PCSU; 2. A receipt is issued to the person handling in the samples; and 3. The name of the supplier and tender reference number on the package of the sample received.

Appellant holds that this is just a modus operandi of procedures that are used within the CPSU and not what happened in the chain of custody of the product.

Dr. Galea explained that the main problem is that in spite of Mr. Ghigo's testimony, the box involved does not belong to ProCare Ltd., as ProCare's material was presented not in a box but in a DHL yellow basket. Appellant holds that Mr. Ghigo did not explain who brought what and who handled what. The document, two receipts, one for ProCare and another of OK Medical Ltd together with a photo of a box were shown. Dr. Galea insists that the box shown online in the first sitting was white and had no markings on it. Dr. Galea insists that this is not the same box that Mr. Ghigo on Oath referred to in the first sitting. The one presented to the Board in this sitting is different. As a consequence, the appellant believes that both boxes do not even belong to the Appellant, hence the present complicated process.

Dr. Galea maintains that either Mr. Ghigo gave testimony on another box, or the box presented was tampered with after.

At this point, the Chairman remarked that since the first sitting was held online one can easily check with the video of that sitting.

A discussion about the procedure adopted in both hearings ensued together with the difficulty of distinguishing between the initial statement made by Dr. Galea and whether the witness was to continue being asked further questions.

Following a decision by the Chairman, the Board conceded to Dr. Zrinzo's wish to present her submission.

Referring to the documents presented during this sitting, Dr. Zrinzo remarked that the contracting authority was asked by the Board during the first sitting to explain how the process of the chain of custody is done. She insisted that the contracting authority complied by presenting policy note no. 11 and policy note no. 39 together with an explanation of how the process of a chain of custody is done and also together with a copy of the receipt itself. The contracting authority was not ordered and obliged to produce an affidavit or witnesses regarding the process involved in this particular case but what the policy is, what are the SOPs, and what the rule says what happens when a sample is accepted. Dr. Zrinzo insisted that the box seen online in the first sitting is the same box presented in this second

sitting. She also contended that it is up to Dr. Galea to ask the relevant questions to Mr. Ghigo as his examination of the witness was still ongoing. She reiterated that the box presented in the first session was also brought to this present hearing.

As Dr. Galea insisted that the PCR B instructions regarding an explanation of the Chain of Custody were not adhered to, the Chairman decided to read out those given in the first sitting. Once read out, Dr. Galea insisted that the instruction of the PCR B were not honoured.

The Chairman then invited Mr. Ghigo to take the stand again under oath since Mr. Ghigo himself, a copy of the receipts and the box in question were present. He also referred to the other issue about the photo taken of the box itself. At this stage, Dr. Galea asked the PCR B to read out the minutes regarding the evidence of Mr. Ghigo in the first sitting since many months had elapsed since then. These were also read out.

(see mentioned minutes of first sitting).

Mr. Ghigo (ID 300874M) was again asked to take the witness stand to continue with his testimony.

Dr. Zrinzo once again insisted that the PCR B provided the document which the Board requested, and that Dr. Galea should continue asking Mr. Ghigo the relevant questions.

Asked about the presented document, Mr. Ghigo confirmed that he saw the document entitled "Chain of custody of samples at the Central Procurement and Supplies Unit" before the present sitting but he had nothing to do with its preparation and that he was an evaluator. He also stated that Randal Williams, the secretary of the CPSU, received the samples of ProCare Ltd. because he checked that he was at work at the reception on that day and indicated that one of the receipts produced by CPSU no. A17264 for ProCare's product carried his signature.

Replying to a question by Dr. Galea about the markings on the presented box and the lack of marks on the presented box online in the first sitting, Mr. Ghigo, showing the box to the Board, confirmed that the box shown online during the first sitting and the one which he brought to the 2nd sitting are hundred per cent the same one as according to him the box shown online had visible markings. This, he said, could be confirmed by the video taken in the first sitting.

At this point, Dr. Robert Galea dictated a note verbal (Verbal submission) which stated that:

*"Acting for the appellant ProCare, Dr. Robert Galea is emphasizing that at this point Mr. Ghigo during his exposition today is insisting that the box he showed during the first sitting on 11th April 2024 is the same box which is in his possession today. However, it must be noted that while it was registered in the minutes of the first sitting that the box had no marks on it, the box shown in this sitting after almost one year, has marks on all four sides together with a label stuck on it. It must be registered that during this period of almost one year there have been no objections about the minutes registered in the first sitting."*

Dr. Zrinzo was also given the right to register a note verbal (verbal submission) in which she stated that this was to refer to the reason why the ProCare bid was refused due to the fact that samples submitted are not compliant with the minimum labelling requirements which are the Batch Number, The Lot Number, The Expiry Date, The Serial Number and the Global Trade Item Number.

The submission states:

*"When we refer to labelling we are referring to what was asked for by the responsible authority as information that has to be fixed on the box and which in this case was missing on the box in question. As regards the argument put forward by Dr. Debono about the lack of demand for the correction of*

*the minutes, it is being submitted that the contracting authority was not in possession of the mentioned minutes before today's sitting."*

At this juncture, the Chairman decided to suspend the proceedings to allow the Board to review the video footage from the initial sitting. This was done to determine whether the box presented in the current sitting was identical to the one observed in the first session.

Following this, Dr. Galea confirmed that he had captured photographs of the box exhibited during the present sitting.

After deliberation, all parties reached a consensus to convene for a third sitting, which was scheduled for March 11, 2025, at 10:30 AM

End of second day of hearing

---

THIRD DAY OF HEARING- 11<sup>th</sup> March 2025

On the 11<sup>th</sup> March 2025 at 10.30 am the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Ing. Damien Gatt and Mr Lawrence Ancilleri as members convened a public hearing to continue considering the appeal following the first hearing held on the 11<sup>th</sup> April 2024 and the second hearing held on the 6<sup>th</sup> March 2025.

The attendance for this public hearing was as follows:

**Appellant – ProCare Ltd**

Dr Robert Galea	Legal Representative
Mr Pierre Calleja	Representative

**Contracting Authority – Central Procurement and Supplies Unit**

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Josette Camilleri	Chairperson Evaluation Committee
Mr Patrick Ghigo	Evaluator
Mr James Said	Representative

The Chairman opened the session by declaring that the Board saw the video mentioned in the second hearing and declares that the box presented in the first hearing is the same that was presented in the second hearing.

Both parties agreed that a verbal submission by both of them declares that all parties saw the mentioned video and hold that:

*"It is agreed that the box which was presented during the second hearing on the 6<sup>th</sup> March and which is presented today is the same box which was presented by Mr Patrick Ghigo during the first hearing held online on the 11<sup>th</sup> April 2024"*

A discussion ensued regarding the procedure adopted during the final segment of the March 6<sup>th</sup> session, during which Dr. Galea interviewed Mr. Patrick Ghigo, who had been called as a witness.

Mr. Ghigo was subsequently recalled to the stand to provide further testimony.

In response to questions posed by Dr. Robert Galea, legal advisor for the appellant, Mr. Ghigo (ID 300874M) confirmed that the box in question was handed to him by Mr. Renald Williams. He acknowledged that the box bore printed information, including two labels with letters and the numbers 5ML/CC. Mr. Ghigo also verified that he personally printed the Reference No. CPSU 5567/23 on the box.

Furthermore, Mr. Ghigo elaborated that the box contained items in a bag labeled with the name ProCare and a CPSU number, in accordance with standard procedure. He stated that he had personally removed the contents from the box.

Mr. Ghigo stated that the CPSU issues a receipt number for the contents, which was likely discarded.

He explained that he first brings the samples, then labels them, and subsequently proceeds to label the next sample from the other bidder.

Mr Ghigo confirmed to the Chairman that the box was handed in another bag.

Asked by Dr Galea about the packaging, Mr Ghigo said that he cannot describe the packaging exactly as a long time had passed. He continued to explain that he put the CPSU number and wrote the name of ProCare and saw that everything was in order. He continued that the syringes are still in the box and showed one envelope with 5 syringes. He continued that ProCare sent 100 syringes and if he remembers well they were in packaging of ten each. In fact, on the box there is marked that it has 100 pieces and that there was no need to write ProCare on the box.

In response to Dr. Zrinzo, Mr. Ghigo stated that he wrote CSPU Ref No 5567/23 on the box. Receipt A 17264 showed that ProCare was the tenderer and the box contained 100 pieces. He could not recall the type of bag enclosing the box but remembered that other bidders provided different sample quantities.

Dr. Galea asked the witness to examine two receipts, who confirmed that both had the same serial number, 5567/23.

Dr Galea called Mr Pierre Calleja to the witness stand. Mr Calleja, the director of ProCare, stated that he handled the logistics and personally presented the samples in a DHL bag to Relend Williams, as requested by CSPU. He confirmed that sample details come from the item itself. He categorically denied that the box presented belongs to ProCare, as it lacks any manufacturer indications. Mr Calleja explained that typically Mr William writes the receipt number and manufacturer's name on all packs. He added that ProCare submitted over 100 syringes, all labelled in bubble wrap inside the DHL package, with ProCare's name.

Mr Calleja presented a box of ProCare samples that included a reference number, a mark indicating European representation, and a Serial Mark. He noted that the box shown by Mr Ghigo lacked any markings to suggest it was sent by the manufacturer.

Here the witness showed the board an example of their typical manufacturer's sample with their markings.

Dr. Leon Camilleri, legal advisor for CSPU, cross-examined Mr. Calleja. Mr. Calleja stated that he signed receipt A17264, presented 100 samples plus a few more, and handed in a DHL pack containing 100 syringes grouped in sets of ten or five. He emphasized that reference numbers and names were printed on the DHL package.

At this stage, the Chairman requested Mr. Calleja's samples be handed in for photography and custody by the Board.

### **Final Submissions by the Appellant**

Dr Galea stated that Mr Calleja's evidence showed ProCare's manufacturers follow standard labelling procedures, with packaging marked by the brand's name on the DHL pack, unlike the box presented by Mr Ghigo. Dr Galea reiterated Mr Calleja's explanation of the sample handling process.

Dr Galea explained that the main issue was the chain of custody process because the packaging linked to the ownership of ProCare has been apparently thrown away and this means that the evidence has been destroyed. Dr Galea declared that we now depend on what the one who destroyed parts of the evidence, has to say. On the other hand, Dr Galea stated that we have Mr Calleja who insists that the box presented by CPSU does not belong to ProCare and the 100 syringes presented by CPSU before the board are not the same 100 syringes he presented to the CPSU. Appellant therefor contends that the CPSU did not handle the process of sampling, labelling, serial numbers and receipts well. Dr Galea also holds that photos were not taken to expose the reality of the issue and that appellant insists that the box presented by CPSU has nothing to do with ProCare. Furthermore, CPSU should have labelled the CPSU with its receipt number on the box so that one could relate to it to the box in question. Hence the chain of custody has not been proven, and it is up to the CPSU to prove that the samples presented belong to ProCare.

Dr Galea referred to PCRB Case No 1931- CF32020/3432/23 where the objection made by the CPSU was not about the packaging but about the volume. In fact, he stated that the Board was satisfied with the issue of labelling and moved on to examine the technical specification itself which means that the CPSU is not consistent with its decisions.

Dr. Galea highlighted the distinction between medical devices and medicinal devices, noting that this appeal relates to the former. The CPSU is rejecting a technical complaint bid by not using its legal powers and altering technical parameters during adjudication.

### **Final Submissions by the Contracting Authority.**

Dr Leon Camilleri contended that this case has two different versions which are completely opposite to each other and the Board has to choose the correct version. While Mr Ghigo explained how he went through the process leading to evaluation the appellant is contending that the box is not his.

Dr. Camilleri argues that the accuser must provide proof, as the witnesses contradict each other. Though both mentioned Mr. Renald Williams' role, the appellant chose not to call him as a witness.

Dr Camilleri went on to refer to Court Cases when two conflicting versions are involved.

He cited the Case of Maria Xuereb et vs Clement Gauci et no 290/2001/1 decided by the Court of Appeal on the 24<sup>th</sup> March 2004 where the principals involved are relevant to this case. These indicate that either we support the CPSU version regarding the discrepancy about the number of syringes quoted by both parties and the importance to be given to either the reference number or the name of the provider, or the fact that in the absence of agreement Dr Camilleri holds that it is the actor who has to prove his version - which in this case has never been proven.

Dr. Camilleri also referred to Court Case No. 103/2011, John Bonnici vs. Richard Vella, where the Court stated that in situations involving diametrically opposing versions, such as the present case, it is the CPSU that should benefit from the doubt due to the principle of **“actore non probandi reus absolvitur”**.

Dr Camilleri also referred to a court of appeal sentence No 226/2003/1- Corporation of Water Services vs John Mary Caruana where it is stated that the benefit of doubt goes to the "**Konvenut**" (defendant) and proof has to be provided by those who are accusing.

Dr. Camilleri cited the case of Charles Grech vs NMJ Co. Ltd No 19742001, decided on January 14, 2004, where the court stated that no court should be left in such disarray that it cannot make a decision.

Dr Camilleri suggested that the PCRB should take note of these cases and see in whose favour it should decide.

Dr. Camilleri argues that if doubts persist, the contracting authority should not re-assess the bids, and the adjudication board's decision should stand.

Dr Camilleri mentioned three PCRB decisions (No. 1916, 1917, and 1918), in which the Board, under similar circumstances, rejected the appeals and upheld the Adjudication Board's decisions.

Dr. Galea questioned how the appellant could provide proof for something destroyed, noting that Mr. Williams did not need to be called as a witness since the issue was what CPSU did with the samples after they were passed on. If another sample was picked up by mistake, the appellant proved that the correct sample was given, not the one exposed during the hearings.

Dr Camilleri ended his submission by stating that appellants present proof of their objections after a judgement was done by an evaluation committee and not vice versa. The contracting authority stand firm by the decision that the box in question belongs to ProCare.

End of minutes

---

### Hereby resolves:

The Board refers to the minutes of the Board sitting of the 11<sup>th</sup> April 2024, the second hearing held on the 6<sup>th</sup> March 2025 and the third hearing held on the 11<sup>th</sup> March 2025.

Having noted the objection filed by ProCare Ltd (hereinafter referred to as the Appellant) on 23<sup>rd</sup> February 2024, refers to the claims made by the same Appellant with regard to the tender of reference CFT020-3432/23 listed as case No. 1989 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Robert Galea

Appearing for the Contracting Authority: Dr Alexia J Farrugia Zrinzo & Dr Leon Camilleri

Whereby, the Appellant contends that:

- a) ***1<sup>st</sup> grievance - About the factual incorrectness of the reason given -***

Whereas the samples submitted by the Objector were very clearly labelled, as can be seen from the samples which had been provided. It is requested that the relative samples be made accessible to this Honourable Board. This shows that such requirements have indeed been satisfied, and, therefore, that the proposal made by the Objector was technically compliant. Such compliance could very easily be ascertained by a reading of the technical specifications and by examination of the samples submitted with the offer and their relative packaging.

Whereas this begs the question as to how realistic the reason given by the CPSU could be, since establishing technical compliance or otherwise is a mere factual exercise, which should be ascertained objectively.

Whereas, it is evidently clear that the requirement for one to supply details of the Global Trade Item Number (GTIN) would only be applicable where secondary packaging is involved. In this case, such secondary packaging did not feature in the offer made, and this for a very valid reason. In this particular request for offers, samples were requested by the Contracting Authority. In view of the fact that the number requested was that of 100 units, the Objector could not supply the items in the 'secondary packaging' but necessarily had to supply the samples in the number requested, thus extruded from the secondary packaging (where the items are supplied in cases of 2400 pieces, batched in boxes of 100 pieces each). Since this did not include any secondary packaging, requirement to supply the GTIN would not have been necessary.

Whereas, without prejudice to the foregoing, it must be noted that the *DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products* and the *DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use* deal very specifically with 'medicinal products' as defined in the same instruments. The equipment subject of the present tender does not fall within the definition of medicinal products as defined in the same Directive, and therefore, the requirements set down by the said Directive do not find applicability in the present scenario, with the reference being made thereto in Clause 29.6 not being applicable to this particular case.

b) ***2<sup>nd</sup> grievance - About the lack of clarity of the decision -***

Whereas as will be expounded below, a 'reasoned decision' should have certain qualities in order for the decision to be truly deemed as a reasoned one. In this case the reason given is not clear, in that while it first states that "*Samples submitted have no labelling printing on packaging*" (added emphasis), it then goes on to list what details are deemed necessary. Then it goes on to state that "*Samples submitted are not compliant with the minimum labelling requirements*" (added emphasis). This leaves the Objector at a loss as to what the Contracting Authority is trying to communicate; is it being alleged that there was no labelling at all, as seems to be implied in the first part of the decision, or is it

being alleged that the labelling present on the samples did not meet the minimum requirements? What was truly deemed as being missing in this case, if at all? The Objector is left guessing, thus rendering its right to a true and meaningful appeal impossible to exercise. In this regard, the Objector reserves its position and rights at law.

c) ***3<sup>rd</sup> grievance - About the fact that the Contracting Authority acted ultra vires -***

Whereas, without prejudice to the foregoing, this grievance logically follows the last preceding grievance in that for the same reasons expounded above, it transpires that the tender document did not confer upon the Contracting Authority the right to reject offers that were indeed technically compliant, and consequently, in rejecting a technically compliant offer, the Contracting Authority went beyond the discretionary parameters established in the tender document. This is a flagrant breach of the principles of natural justice, and even on this basis, the objector humbly submits that the decision in question should be quashed.

d) ***4<sup>th</sup> grievance - About the fact that the Contracting Authority changed the evaluation criteria and technical specifications while deciding on the Objector's offer -***

Whereas as can be seen from the rejection decision, the basis of the decision was that "Not accepted. Samples submitted have no labelling printing on packaging. Samples submitted are not compliant with the minimum labelling requirements which are the Batch No/Lot Number, Expiry date, Serial number and Global trade item number. These requirements have been requested in the tender dossier Sections 29.5 and 29.6" (added emphasis). While the technical specifications clearly limit certain labelling requirements only to secondary packaging (and which would only be applicable to medicinal devices, which is not the case here), the Contracting Authority in this case opted to apply the same, apparently, across the board without applying the distinction which emanates from the very same tender dossier it refers to in the rejection decision. This means that the adjudication criteria and even the specifications were being changed ex post facto by the Contracting Authority.

Whereas it is not up to the Contracting Authority to make changes to the specifications of a tender at the point when the same is supposed to be subject to adjudication, and consequently the same Contracting Authority acted ultra vires in the determination of the present process.

Whereas, without prejudice to the above, as will be proven in the course of these proceedings, the Objectors has in the past participated in and been awarded various tenders on the basis of specifications being exactly identical to those subject of these proceedings, and there were never any conditions which were introduced by the same Contracting Authority in the course of the adjudication process and which departed from the criteria set in the dossier. Clearly, during the adjudication process, the Specifications as they emanate from the request for offers were ignored, and instead replaced by other criteria which the Contracting Authority deemed fit to apply, rendering the process leading to the exclusion of the Objector ultra vires and therefore null and void.

e) ***5<sup>th</sup> grievance - About the obligation to give reasons for decisions -***

Whereas one of the very basic principles regulating the process where discretion is exercised and consequently a decision given - as is the present case - is the principle of natural justice calling for giving reasons for decisions. This principle of a fundamental nature in the proper exercise of a discretionary power would require that any decision is supported by a line of reasoning which would indicate how that decision was actually reached.

Whereas in this case, there is a manifest and unequivocal breach of this principle since the reasons are to serve as a logical explanation of the decision. Such reasons should follow a logical path, culminating in the decision itself. However, as indicated above, the reasons given are factually incorrect (as indicated in the grievances raised supra) and do not follow a logical course. In view of such failures, the reasons given for refusal fall short of the quality that reasons should have in order to truly qualify as reasons for the purposes of law.

Whereas in view of the above, one cannot conclude that the decision was reached in a manner whereby the logical reasoning leading to the decision could be traced, and consequently, the decision is to be considered as being in breach of the principles of natural justice and thus, the Objector humbly submits, is subject to being quashed.

f) ***6<sup>th</sup> grievance - About the obligation to exercise discretion in a just and proper manner -***

Whereas furthermore, the principles of natural justice dictate that if there is a discretion that is to be exercised, this must be exercised in an informed and just manner in order to lead to an equitable, just, logical and predictable outcome. Justice must not only be done, but it must also be seen to be done, and the circumstances of the present case do not give much comfort to such a principle which is at the very basis of the rule of law. The existence of discretion brings along the duty to actually i) exercise such discretion and ii) to exercise it in a just and informed manner. In this case, the Objector humbly submits that i) the approach taken in arriving at the decisions and (ii) the decisions themselves, clearly indicate that the discretion that had to be exercised by the Contracting Authority was not exercised in a proper manner, as the decisions do not follow in a logical manner the facts that were available to the Contracting Authority during the adjudication process and procedure was not followed. Consequently, the decisions are not intelligible and cannot be traced back logically to the facts upon which they were supposed to have been based.

g) ***7<sup>th</sup> grievance - About the fact that the Contracting Authority did not act according to procedure -***

Whereas moreover the Objector humbly submits that in the event that the above grievances / submissions are not upheld, the Board should also consider whether the Contracting Authority and / or the Evaluation Panel acted according to the rules and regulations governing this particular procedure.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 4<sup>th</sup> March 2024 and its verbal submission during the hearing held on 11<sup>th</sup> April 2024, the second hearing held on the 6<sup>th</sup> March 2025 and the third hearing held on the 11<sup>th</sup> March 2025, in that:

a) ***On the First Grievance - About the Factual incorrectness of the reason given -***

In its first grievance the objector states essentially that it is not true that the product offered does not have labelling on the packaging, and goes on to say that the samples submitted are very clearly labelled. The samples handed to the evaluation committee were individually packed in a blank packaging without a single word printed on the packaging as will be demonstrated to this Honourable Board. Moreover, the secondary packaging also does not include the labelling as requested for medical devices. The objector attempts to disregard the primary packaging of each and every syringe and consider the secondary packaging as the bulk packaging. This is not permissible and is factually incorrect. The bulk packaging as described by the objector is a pack of 2400 syringes. From a practical point of view, a ward, let alone a nurse, will not be given a pack of 2400 syringes, and thus it is essential that the information requested by the tender document is on each and every packaging of individual syringes. Moreover and without prejudice to the above, the tender document clause 29.6 of the Special conditions requires that labelling is on each and every product, and not on the secondary packaging. The contracting authority is by no means considering the product as a medicinal product, however it is undauntedly a medical device and the offered product also fails to meet the regulations applicable for medical devices, particularly those relating to packaging. Without prejudice to the above, the main point of this objection and of the evaluation remains that the labelling above mentioned in paragraph 6 is requested for each product and the objector failed to provide this.

b) ***On the Second Grievance - About the lack of clarity of the decision -***

In its second grievance the objector claims that the decision of the contracting authority was not clear in its reason for refusal provided. The objector goes on to state that "samples submitted have no labelling printing on packaging" and "samples submitted are not compliant are not compliant with the minimum labelling requirements" are contradictory and left the objector at a loss. If there is a party that should know the product well, this is the objector and the contracting authority is to say the least, very surprised by these claims. If the product does not have any labels printed, how can it ever meet the minimum label requirements? This is natural and logic and the contracting authority does not see any ambiguity and lack of clarity in all of this.

c) ***On the Third Grievance - About the fact that the Contracting Authority acted Ultra Vires -***

In its third grievance the objector states that the tender document did not confer upon the contracting authority the right to reject technically compliant offers. This is factually incorrect as the contracting authority can reject technically compliant offers if there are cheaper technically compliant offers. Subordinately, if what the objector meant was that the contracting authority cannot reject compliant offers on the basis of non-compliance, CPSU naturally agrees, however in

this case, as already explained, the objector's product was not compliant and thus CPSU acted correctly and definitely did not act ultra vires.

d) ***On the Fourth Grievance - About the fact that the contracting Authority changed the evaluation criteria and technical specifications while deciding on the Objector's offer -***

In its fourth grievance objector states that contracting Authority changed the evaluation criteria and technical specifications. CPSU rebuts this unfounded claim which was not substantiated in any way. In part of this grievance objector says that the syringes offered are not medical | devices, which leaves CPSU wondering as to what these syringes are. Syringes are from their very nature medical devices classified in class 1 or Class IIa under the Medical Devices Regulations and what the evaluation committee did was, apply the tender conditions applicable to medical devices, and to conditions applied for all products supplied, in full respect to all the general procurement.

e) ***On the Fifth Grievance - About the obligation to give reasons for decisions -***

In its fifth grievance the objector submits that the contracting authority failed to give reasons for its decision. CPSU respectfully submits that if the contracting authority failed to give reasons for its decision, a 9-page letter of appeal on substantive grievances would surely not be possible. As this Honourable Board will surely note, the evaluation committee did give sufficient reasons for the rejection of the objector's offer as required by law and in line with all the principles of administrative and natural justice.

f) ***On the sixth Grievance - About the obligation to exercise discretion in a just and proper manner -***

Had the rejection been on the basis of sample testing, debating the extent of the evaluation committee's discretion would have been much more understandable. Whilst definitely acknowledging the fact that evaluation committees have an element of discretion in their evaluation process, this is limited especially in this case and similar cases, where the product is deemed not to be compliant not due some failure during the use but do to criteria which can be objectively ascertained. If the tender document is requesting that the medical devices are labelled in accordance with legislation in force and that the elements of clause 29.6 should have been fulfilled, and the product supplies does not even have a label, then discretion plays a little role, if it plays any role at all, as the decision was taken on objective grounds.

g) ***On the seventh Grievance - About the fact that the Contracting Authority did not act according to procedure -***

As the objector fails to substantiate or at least explain this grievance, CPSU rebuts as unfounded in fact and at law and for this reasons, this seventh grievance ought to be rejected.

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.

### **Chain of Custody Issue**

The Board notes that a central issue in this case concerns the chain of custody of the sample syringes submitted by the Appellant. Through three hearings (11<sup>th</sup> April 2024, 6<sup>th</sup> March 2025, and 11<sup>th</sup> March 2025), conflicting testimony was presented regarding the packaging and labeling of the submitted samples.

Mr. Patrick Ghigo testified that he received samples in a box which lacked proper labeling, while Mr. Pierre Calleja, director of ProCare, testified that samples were submitted in a properly labeled DHL bag. Despite both parties eventually acknowledging that the box presented in the hearings was identical to the one shown in the first hearing, they maintained fundamentally different positions regarding whether this box belonged to ProCare.

The Board acknowledges that in cases with conflicting testimonies where conclusive evidence is lacking, established jurisprudence, particularly *Maria Xuereb et vs Clement Gauci et (290/2001/1)* and *John Bonnici vs. Richard Vella (1032011)*, places the burden of proof on the party making the assertion. For example, in *John Bonnici vs. Richard Vella (1032011)*, the Court affirmed: *"Il-piż tal-prova tad-dinamika tal-incident huma fuq l-attur u mbux fuq il-konvenut. Dan tal-abbar ma kellu għalfajn iressaq l-ebda prova; għaliex l-attur naqas li jipprova l-allegazzjonijiet tiegħu."*

Furthermore, the Board also notes relevant precedents in PCRB Case 1916,1917 & 1918 where under similar circumstances involving disputed sample evidence the Board emphasized that *"the sample that is to be used as reference for the proper evaluation of this tendering procedure, is that as submitted during the evaluation stage"*.

Based on these principles, the samples shown by the Contracting Authority during the hearings will be used by the Board to evaluate the seven grievances put forward by the Appellant. The alternative box of samples presented by Mr. Calleja during the third hearing cannot be considered at this point in the proceedings.

### **Responses to Grievances**

#### **First Grievance – About the factual incorrectness of the reason given**

- The Appellant contends that the samples submitted were clearly labeled and technically compliant with the tender requirements.
- The testimony of Mr. Ghigo, who was directly involved in the evaluation process, demonstrated that the samples lacked the mandatory labeling requirements.

- The Board notes that the Appellant has failed to conclusively establish that the samples submitted contained the required labeling as specified in Sections 29.5 and 29.6 of the tender document.

Therefore, the Board does not uphold the Appellant's first grievance.

### **Second Grievance – About the Lack of clarity of the decision**

- The Appellant argues that the CPSU's decision lacked clarity, particularly in stating both that "*samples submitted have no labelling printing on packaging*" and "*samples submitted are not compliant are not compliant with the minimum labelling requirements*" are contradictory and left the objector at a loss.
- The Board finds that these statements are not contradictory but complementary. The absence of labeling logically means non-compliance with minimum requirements. The decision clearly referenced the specific sections of the tender document (29.5 and 29.6) that were not complied with.

Therefore, the Board does not uphold the Appellant's second grievance.

### **Third Grievance – About the fact that Contracting Authority acted ultra vires**

- The Appellant claims that the Contracting Authority exceeded its powers by rejecting a technically compliant offer.
- The Board opines that the CPSU acted within its authority and applied the evaluation criteria specified in the tender document (more specifically clauses 29.5 and 29.6 of the tender dossier.

Therefore, the Board does not uphold the Appellant's third grievance.

### **Fourth Grievance – About the fact that the Contracting Authority changes the evaluation criteria and technical specifications while deciding on the Objector's offer**

- The Appellant alleges that the Contracting Authority altered the evaluation criteria by applying labeling requirements beyond those specified in the tender.
- The Board finds no reason at this stage to question the Contracting Authority regarding '*Syringes are from their very nature medical devices classified in class 1 or Class IIa under the Medical Devices Regulations and what the evaluation committee did was, apply the tender conditions applicable to medical devices, and to conditions applied for all products supplied, in full respect to all the general procurement.*'

- The Board therefore finds no evidence that the evaluation criteria were changed during the process, and that the evaluation was not performed in accordance with the original criteria established in the tender documentation.

Therefore, the Board does not uphold the Appellant's fourth grievance.

#### **Fifth Grievance – About the obligation to give reasons for decisions**

- The Appellant contends that the Contracting Authority failed to provide adequate reasoning for its decision.
- The Board determines that the CPSU's explanation was sufficiently detailed making specific reference to "*the minimum labelling requirements which are the Batch No/Lot Number, Expiry date, Serial number and Global trade item number*" and citing the relevant sections of the tender dossier : "*Sections 29.5 and 29.6*"

Therefore, the Board does not uphold the Appellant's fifth grievance.

#### **Sixth Grievance – About the obligation to exercise discretion in a just and proper manner**

- The Appellant claims the Contracting Authority failed to exercise its discretion in a just and proper manner.
- The Board opines that the decision taken by the Contracting Authority was taken on objective grounds, as explained in the responses to the previous grievances.

Therefore, the Board does not uphold the Appellant's sixth grievance.

#### **Seventh Grievance – About the fact that the Contracting authority did not act to procedure**

- The Appellant alleges that the Contracting Authority did not act according to procedure.
- In the absence of concrete evidence demonstrating procedural irregularities, this Board cannot uphold a general claim of improper procedure.

Therefore, the Board does not uphold the Appellant's seventh grievance.

**The Board,**

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

- a) Does not uphold Appellant's Letter of Objection and contentions,
- b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,
- c) Directs that the deposit paid by Appellant not to be reimbursed.

**Mr Kenneth Swain**  
Chairman

**Mr Lawrence Ancilleri**  
Member

**Dr Ing. Damien Gatt**  
Member