PUBLIC CONTRACTS REVIEW BOARD

Case 1996 – CT2238/2023 – Supplies – The Supply, Delivery and Distribution of Incontinence Products for Senior Citizens and Persons with Disabilities in Malta – Active Ageing and Community Care – Lot 1

3rd June 2025

The Board,

Having noted the call for remedies filed by Dr Matthew Paris on behalf of DalliParis Advocates acting for and on behalf of Pharma-Cos Limited, (hereinafter referred to as the appellant) filed on the 20th October 2023;

Having also noted the letter of reply filed by Dr Noel Bezzina acting for Active Ageing and Community Care (hereinafter referred to as the Contracting Authority) filed on the 25th October 2023;

Having also noted the letter of reply filed by Dr Daniel Inguanez acting for the Department of Contracts (hereinafter referred to as the DoC) filed on the 25th October 2023;

Having also noted the letter of reply filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja on behalf of Ganado Advocates acting for Krypton Chemists Limited (hereinafter referred to as the Interested Party) filed on the 30th October 2023;

Having heard and evaluated the testimony of the witness Mr Julian Fearne (Representative of Medicines Authority) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Ms Marisa Cassar (Representative of the Contracting Authority) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Mr Gordon Zammit (Representative of Pharma-Cos Limited) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Mr Matthew Arrigo (Representative of Krypton Chemists Limited) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

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 sittings of the 18th April 2024 and 6th June 2024 hereunder-reproduced.

Minutes

Case 1996 – CT 2238/2023 – Supplies – The Supply, Delivery and Distribution of Incontinence Products for Senior Citizens and Persons with Disabilities in Malta – Active Ageing and Community Care - LOT 1

Remedy before Closing Date of a Call for Competition.

The tender was issued on the 11th August 2023 and the closing date was the 30th November 2023

The estimated value of this tender for Lot 1, excluding VAT, was € 438,700.

On the 20th October 2023 Pharma-Cos Ltd filed an appeal seeking a remedy under Public Procurement Regulation 262 against the Active Ageing and Community Care (AACC) objecting to the terms of the tender document on Lot 1

A deposit of € 2,193.50 was paid on this lot.

On the 18th April 2024 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Dr Vincent Micallef as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma-Cos Ltd

Dr Matthew Paris	Legal Representative
Dr Zack Esmail	Legal Representative
Mr Gordon Zammit	Representative
Mr Marcel K Mifsud	Representative

Contracting Authority – Active Ageing and Community Care

Dr Noel Bezzina	Legal Representative
Dr John Gauci	Legal Representative
Dr Rachel Powell	Legal Representative
Ms Rita Tirchett	Representative
Mr Alexander Vella	Representative
Ms Mary Grace Balzan	Representative
Ms Marisa Cassar	Representative

Interested Party – Krypton Chemists Ltd

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

Interested Party – Drugsales Ltd

Dr Douglas Aquilina	Legal Representative
Ms Gulia Attard Montalto	Representative
Mr James Borg	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative
Dr Audrey Marlene Buttigieg Vella	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and prior to inviting submissions, gave a summary of the urgent applications filed by both appellant and Krypton Chemists Ltd (Krypton) apart from the call for remedies and the urgent application of the 8th January 2024 in accordance with Regulation 262. The Board will hear the parties on the urgent applications that deal with tender CT 2238 first and then go on to the Negotiated Procedure if time allows.

At the request of the Board the parties agreed that the decision on both above cases will be published simultaneously even if this exceeds the statutory time limit.

Dr Matthew Paris Legal Representative for Pharma-Cos Ltd referred to the urgent application of the 8th January 2024 requesting cancellation of the tender, in line with Regulation 266.03. Since then, a new procedure has been introduced by the Department of Contracts (DoC) which has removed the problem and the application had therefore been lifted. [Copy exhibited]. A second application dated 3rd April 2024 requested the Board to determine that Krypton's application of the 30th October is *fouri termine*. Regulation 264 (which was read out) is very clear on this point. The sequence of events was that on the 20th October 2023 Pharma-Cos filed an application for a remedy. The AACC and the DoC both replied on the 25th October, all according to regulations, whereas Krypton's reply was not filed till the 30th October and well outside the regulations. There are a number of previous decisions on the point of late submissions and the peremptory period allowed, including the recent *Hitachi vs DoC* case. Pharma-Cos is requesting that Krypton's request is not considered and should not even be discussed. There is a second point regarding interested parties, namely, that any submissions by them must only deal with the process in hand and they cannot introduce new matters.

Dr Paris pointed out that the use of certain language and unnecessary comments in submissions made to the Board are regulated by law (Article 159 of the COPC) and should be purged from the records. Regarding the invitation by Krypton to the Board to decide if the mandatory injunction was frivolous, the appellant maintains that if the Courts did not pronounce on this it must have felt that it was not the case. Krypton are now trying to 'hijack the system' but this is not a matter for the PCRB to decide but for the Court of Appeal.

A reply to a Regulation 262 application must be filed within five days, continued Dr Paris, and the PCRB has to decide on this point – the claim that this request is frivolous is inadmissible as this can only be claimed through the Courts. Regarding the procedure on the time limit, in the first instance in a situation of inadmissibility the first step is to make an application to be allowed to act. This as stated in the *Wirt Artna* Court of Appeal Case 1145/2018GM. One cannot act without a previous application and following that one has to make a case to persuade that action is taken. The only exception to this is in Article 728 of Cap. 12 of the Civil Law. The Appellant requests that the claim of inadmissibility is expunged. The PPRs are clear that the only way of knowing what is happening is by being vigilant. In the previous cases heard on this matter Pharma-Cos failed to appeal against the decision to split the tender into lots as they were not aware of the decision and consequently 'they missed the bus' – similarly in this case this has happened to Krypton.

Dr John Gauci Legal Representative for the Contracting Authority stated that the Authority refers to what the law states regarding the right of reply and specifically that it states that this is a 'may' situation. However, there is always the opportunity to appear before the Board and make the case then, as the PPRs do not limit interested parties from participating. In the *Hitachi* case referred to earlier additional grievances were allowed to be added. If the Krypton application is *fouri termine* it is up to the Board *ex officio* to decide the circumstances after hearing the parties.

Dr Mark Anthony Debono Legal Representative for the Department of Contracts stated that according to Regulation 90 the parties can make their submissions at any stage. The PCRB has no power to order the extraction of documents not submitted in time.

Dr Clement Mifsud Bonnici Legal Representative for Krypton Chemists Ltd said that in view of certain earlier comments he would point out that the usual procedure is that reference is made to parties not to individuals as those individuals are acting on behalf of clients. The injunction documents submitted to the Board where exactly as provided by the Courts and folio 65 clearly shows the withdrawal of the injunction. Appellant has given his strategy away, namely that it will do anything to hold on to the tender as the incumbent and does not relish any pressure through having competition.

This is a cart before the horse situation, said Dr Mifsud Bonnici, as Appellant cannot ask that Krypton claim cannot be considered when Pharma-Cos themselves should not even have sought this remedy – a totally surreal situation. The tender should not have been suspended as the application was *fouri termine.* The other parties replied within five days as they were notified, unlike Krypton which were not advised. Although the situation has now changed, at that time no notification was posted that a precontractual remedy had been filed. It is therefore unjust if the application is ignored.

Dr Mifsud Bonnici detailed the process from the issue of the tender which laid down a first deadline of 5th October with the injunction used as a pretext to re-open the tender due to the actions of the DoC. In reality the tender was frozen. The interested party has the right to make submissions and the Board should not direct the expunging of their application since it still has all the rights.

Dr Paris referred to PCRB Case 1812 *Prohealth vs DoC* where attempts were made for new grievances to be introduced but these were denied by the Board after objections were raised. Pharma-Cos are not asking that the parties be removed and not allowed to participate but simply that they be not allowed to make any applications.

Dr Mifsud Bonnici said that removal was precisely what Pharma-Cos did demand as in their submission they claimed that Krypton has no legal standing.

The Chairman proposed a short recess to enable the Board to consider the points made.

On resumption the Chairman stated the following:

"The Board first of all considered Appellant's request to have the reply of Krypton Chemists Ltd expunged from the records. At this stage the Board feels that such a request should not be granted and this in view of the specific and exceptional circumstances peculiar to this case. This is a case in which even the Department of Contracts deemed the need to modify the ePPS system so that similar incidents like the present would not recur again. This fact is evidenced by the document which the Department of Contracts tabled at this sitting as well as the confirmation of the appellant itself which confirms this outcome. It is, therefore, just and equitable that the reply of Krypton Chemists Ltd should still form part of the submissions in this procedure.

Moreover, continued the Chairman, the Board refers to the question raised regarding the submission of documents *fouri termine* which is a matter of a public nature since this Board has the power of dealing with this point *ex officio*. This matter was addressed in the Court of Appeal case *Salina Wharf Marketing Limited vs Malta Tourism Authority* [Lower Civil Court decided on the 12th July 2007] and also in *Giuseppina Caruana vs Charles Psaila*, Lower Civil Court decided 21st March 1997 as well as in the sentence in the Appeal *A.B. vs Commissioner of Inland Revenue* decided on the 9th May 2007. Bearing in mind the exceptional circumstances peculiar to this case, the reasoning applied in the first instance in dealing with the application against Krypton Chemists Ltd must be followed in the

application by Krypton Chemists Ltd against the appellant's application and which must therefore likewise still form part of the submissions in this case. This will ensure that both parties are being treated equitably.

The Board will now hear the merits of the case."

[Dr Gauci asked to be excused due to a prior commitment and left the hearing].

Dr Paris stated that he will first of all deal with the application under Regulation 262. There are several ways in which the Board can deal with the appellant's application, among them cancellation or clarification. It is not right to claim that this is an attempt by Pharma-Cos to hold on to the incumbency since they have the same rights as all the other parties. They sought several clarifications with no response forthcoming which ultimately forced them to seek the Regulation 262 application. There is no requirement, as claimed by the DoC, that every grievance raised has to be based on a point of law. One of the proposals of the *Bonello Commission* was that grievances have to be tied to a point of law but this proposal was never implemented and hence is not in force. There are several instances where this Board has heard half-baked appeals simply because the legislator did not put limits on appeals and it would be impossible for the Board to carry out its functions on the lines that the DoC requires.

There is no ambiguity, said Dr Paris, in how grievances should be dealt with and addressed through the tools of clarifications and appeals which are neither exclusive nor mandatory and one route can be taken following another. It is up to the appellant to decide which route to take. Some of the clarifications sought by appellant have been replied to whilst others are still unanswered or half answered. There is lack of clarity in the Financial Bid Form in differentiating between units and packs and disregard to the Guidance for Good Distribution – the replies offered varied from: this document is only guidelines, to this is not a medical device, to it is none of your business. The third point is that the Technical Offer Form has an inconsistency between the requirements of the tender and what is required in the Form. Certain aspects of the technical specifications are ambiguous and there is a lacuna – so please remove all ambiguities to avoid problems. The other points raised are by way of suggestions which can be accepted or not. The difference in how the tenders were drafted is illustrated in paragraph 3.3 of appellant's letter of objection but the main gripe is regarding the distribution since this is covered by regulatory requirements for medical devices.

Dr Noel Bezzina Legal Representative for the Contracting Authority said that the objection by Pharma-Cos was outside the statutory time limit. The tender was published on the 11th August and if you take into consideration all the extensions it closed at the end of October. The ⅔ limit would be the 4th October as contrary to what Pharma-Cos claim the injunction period has to be considered as part of the tender timeline. The Contracting Authority is saying that on the 5th October it was no longer possible to use this procedure and anything that hapneend after that date is *fouri termine*. No grounds were stated on which grievances under Regulation 262 were based and one needs to indicate clearly what one is requesting otherwise the Board has nothing to decide and conclude on. The basis of the grievances are unclear and should not be considered by the Board.

Dr Debono stated that without specific reference to grounds the Board cannot properly decide. Cancellation can be demanded only on breaking of a law according to Regulation 262(e). As regards the question of distribution, Pharma-Cos as an established commercial enterprise is fully aware of normal commercial practice in this respect. As to whether the product in question is a medical device, this is up to the appellant to establish. It is the service that determines the procurement process so that if this is contract for supplies then the call is correct.

Dr Mifsud Bonnici said that Krypton relies on the submissions of the Authority with regard to the grievances which must follow one of the five grounds laid down in the law. PCRB Case 1964 was cited in the context that Krypton had full expectation to compete and still hopes to do so. There is nothing wrong in being the incumbent supplier but this creates special obligations to the market and certain actions are not permissible and various regulations tie one down. Only one out of ten grievances was raised in the clarifications sought and yet appellant complains that no answers were received. The tender must proceed as such to enable economic operators to participate in the call.

Mr Julian Fearne (102894M) called to testify by appellant stated on oath that he was the Senior Head of the Malta Medical Devices Authority, that he was a Chemist by profession and was on the point of completing a Ph. D qualification in medical devices. He explained that medical devices were regulated by the EU and that Malta has the Medicines Act legislation which regulates economic operators in medical devices including licences, registrations, manufacturing and competence. Witness was referred to the guide on medical devices and he explained the purpose thereof and said that in this case the purpose of the guide was in dealing with distribution standards. Sanctions were applied by the Authority in cases where regulations were not followed and there are penalties for infringements but if possible the Authority sought amicable settlements. [Witness was referred to a copy of the tender and asked to comment if the products shown were medical devices]. Witness stated that the term incontinence products is a very vast subject and it was up to the manufacturer to declare if the product was a medical device, although the definition of a medical product is in the legislation. The items listed in the tender could be either medical devices or not – the majority of items could generally be considered as medical devices with the greater possibility being that the inco sheets are medical devices – the other products depend on how they are classified by the manufacturer. Questioned further witness said that the Medical Devices Co-ordinating Group (MDCG) is an organisation of competent authorities of EU member states which offers guidelines on products and is there to clarify grey areas in regulations or discrepancies between member states so as to achieve unanimity. Witness further stated that the guides are not legally binding. A Unique Device Identifier is issued to enable the public to identify if a product is a medical device but generally lay persons would find it difficult to identify products.

Questioned by Dr Bezzina, witness confirmed that the guidelines are not legally binding. Referred to the Good Distribution Practice witness said that this is EU endorsed and treated as law in good faith. Malta has the right to issue its own guidelines. Sanctions can be taken either on points of law or on the guidelines.

In reply to a question by Dr Debono, witness said that the legislation was highly technical and he was not prepared to comment on a case by case basis.

This concluded the testimony of Mr Fearne.

At this stage the Chairman thanked the parties and adjourned the hearing to the 13th May 2024 at 9.00am.

End of Minutes of first sitting.

SECOND HEARING

On the 6th June 2024 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Dr Vincent Micallef as members convened a public hearing to further consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma-Cos Ltd

Dr Matthew Paris	Legal Representative
Mr Gordon Zammit	Representative
Mr Marcel K Mifsud	Representative
Mr John Soler	Representative

Contracting Authority – Active Ageing and Community Care

Dr Noel Bezzina	Legal Representative
Dr John Gauci	Legal Representative
Dr Rachel Powell	Legal Representative
Ms Rita Tirchett	Representative
Mr Alexander Vella	Representative
Ms Mary Grace Balzan	Representative
Ms Marisa Cassar	Representative

Interested Party – Krypton Chemists Ltd

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

Interested Party – Drugsales Ltd

Dr Douglas Aquilina	Legal Representative
Ms Gulia Attard Montalto	Representative
Mr James Borg	Representative

Department of Contracts

Dr Daniel Inguanez	Legal Representative
Dr Mark Anthony Debono	Legal Representative
Dr Audrey Marlene Buttigieg Vella	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and noted that this is the second hearing of this call for remedy application and the Board had started hearing witnesses when the first hearing was adjourned.

Dr Paris asked for further witnesses to be heard.

Ms Marisa Cassar (388175M) called to testify by appellant stated on oath that she is a Procurement Officer at the AACC and was responsible for drafting the tender. She said that what the AACC required was incontinence products and hence the specifications were dictated by specialists in such products. The only guide given in this respect was a requirement that the product had to follow CE marking regulations. The specifications were also requested in the technical literature. Replies to clarification requests were discussed by individuals concerned but drafted by one of her colleagues. Referred to

Clarification 4 question 2 enquiring if beneficiaries would be receiving full packs and loose nappies, witness stated that the reply was exactly as the answer provided [which was read out]. The quantities were as indicated on page 10 of the dossier and the minimum buffer quantities requirement applied to all.

In reply to a question from Dr Bezzina, witness said that the minimum quantities required were as indicated in the tender dossier and that the incumbent, now appellant, met all the requirements of the previous tender.

Replying to questions from Dr Mifsud Bonnici, witness replied that the 2017 tender was used as the basis of this tender and confirmed that the unit cost price per item was requested in that tender and applies also to this tender under review. There were no objection raised in the case of the 2017 tender which was awarded to Pharma Cos.

Mr Gordon Zammit (276670M) called to testify by the appellant stated on oath that he is the Chief Operating Officer at Pharma Cos, that he is a Pharmacist by profession and has 25 years' experience in the distribution business. As incumbents, appellant is fully aware of problems that exist at present. The 2017 tender and the present one are totally different and cannot be compared. New regulations which are binding have come into force since the previous tender and these have to be followed. According to the witness, ethics prevented him from providing open packs of loose nappies. The CE mark binds the distributor to provide the product in pack form, and there is therefore difficulty in meeting the requirements of the tender in its present form, hence the need for the appellant to seek a clarification (Number 4.2). The point of that was to establish if the tender was following the stipulated requirements or not. There is also a logistical point as to the correct quantities given unless the packs are broken into. The number of beneficiaries run into thousands so one is talking about large figures.

The web application said the witness was something introduced in this tender and the request for a 'demo' was a new concept that had to be built up from scratch. In regard of this demo there was no information provided on the number of users, no number of device accesses and therefore no basis to build the software and no indication of the server to be used. The specifications in Section 3 (pages 19, 20 and 21) offer the criteria for guidelines but are not part of the technical offer which states which parts are mandatory.

Questioned by Dr Gauci, witness stated that nappies are medical devices so the beneficiaries' requirements cannot be honoured unless packs are opened. The requirement of the minimum buffer stock creates difficulties if it does not match patients; requirements unless the quantity is stated in packs. Pharma Cos, confirmed the witness, are the present incumbent and feel that the practice of providing users with loose items is unethical.

Dr Paris objected to this line of questioning which he claims might incriminate witness and directed witness not to answer.

[Witness was requested to leave the sitting to enable lawyers to make legal submissions].

Dr Gauci said that witness had raised the point of ethics and stated that he felt that he is breaking the guidelines and therefore lawyers are entitled to ask questions on this point.

Dr Paris said that witness spoke about ethics and not about breaking the law.

Dr Mifsud Bonnici made the point that witness was being cross-examined and therefore it was possible and in order to ask such questions which should be allowed.

The Chairman directed that questions on the point of ethics and guidelines are to be allowed to be asked.

[Witness resumed his testimony]

In reply to further questions from Dr Gauci, witness confirmed that he felt that he was being unethical and not observing the guidelines in providing loose items. Asked if he had raised this point with the Authority, witness said that he had only had informal contacts and had taken no action to stop the current contract. Dealing with the question on the web application, witness said that appellant had presently an operating application but this was not as requested in the tender and the requirement for the demo were not clear to the extent that he could not obtain a quotation for it from any supplier as they claimed there were too many unknowns to enable them to supply a quotation. Witness confirmed that appellant had not sought any clarifications on this point.

Questioned by Dr Mifsud Bonnici, witness said that he has been employed by Pharma Cos for five years and confirmed that the web application was included in the specifications (page 20). Witness said that he does not know the names of the firms he contacted regarding the web application.

When questioned by Dr Aquilina, witness said that he had had consultations with the Medicines Authority but not with the Contracting Authority on the ethical points he had raised. He confirmed that appellant regularly supplied both packs and loose units and that no one had stopped it and this point had never been raised by the Authority but had only come up now at this stage. Witness insisted that packs with the CE mark must not be split as this is a medical device and it is up to the individual dispenser how it is supplied.

Mr Matthew Arrigo (188094M) called to testify by the appellant stated on oath that he is the Business Development Director at Krypton Chemists and confirmed that his firm had not participated in the injunction process.

Dr Mifsud Bonnici requested that it be minuted that Krypton Chemists were not party to the injunction and had no right to participate in the process.
This concluded the testimonies.

Dr Paris said that in regard to the matter of inadmissibility of the application objection, the DoC claim that appellant did not explain under which articles of the law its appeal was based. The objections were very clear on the substantial points – other points were simply one that could have been taken into consideration. The other side is trying to ignore the exact wording of Regulation 270 demanding reasons for the appeal to be specified in a very clear manner. Conversely the wording of Regulation 262 is different and there is no requirement for 'very clear'. The expectation of the law in Regulation 262 is different and all that is required is a reasoned application. Again, if one refers to Regulation 209 it clearly requests full detail of what is required and again Regulation 282 requires mandatory requirements to be admissible. It is, therefore, very clear that if the law wants it to be stated it says so and if it is not stated then one cannot assume it. In this case we are referring to Regulation 262

where there are no such requirements and therefore the extensive arguments put forward regarding inadmissibility do not hold water.

When one considers the inadmissibility on Krypton Chemists reply, said Dr Paris, the law is clear that to participate in the first phase of the written submissions one has to adhere to certain particular terms. The PCRB and the Court of Appeal have both accepted that these terms can only be widened in one particular circumstance and that is if the appellant discovers facts that emerge later but this cannot extend to written submissions to be allowed after the statutory term. This is clear and distinct. The second point raised on the inadmissibility is that the injunction was a process which is not denied by PPRs. The Court did not state that this process was an abuse of proceedings and once the period of reply was extended the injunction was withdrawn. The other party could well have pleaded to intervene. The PCRB cannot declare, as requested, that the Court injunction was frivolous and vexatious.

Dealing with the matter as to whether incontinence products are medical devices, Dr Paris stated, that two opinions had been heard on this point. Mr Fearne had said that it was difficult to determine if the product is a medical device or not as such indication is only displayed on the product itself, but also stated that he is not aware of products that are not medical devices. This contradicts two points made by the AACC which claims that incontinence products are not deemed to be medical devices ignoring completely the fact that they were requesting provision of a product which is classified as a medical device under the Medicines Act. If they had realised this the drafting of this tender would have been different. This tender cannot be based on the previous tender since in the meantime there has been a change of regulations – one here is not talking of guidelines but of regulations. This situation can be related to an ECHR decision on the IVF case where the wrong interpretation of a protocol article was treated as the same as if the law had been wrongly interpreted.

According to the testimony of Mr Fearne, said Dr Paris, the present tender as issued was under different regulations as new regulations are now in force and are there to establish standards. AACC has ignored this and both they and the DoC did not seem to understand what they were acquiring. There are difficulties in fulfilling this contract – for a start the numbers requested by the Authority may not tally with the number of packs and once a pack is open the CE mark no longer applies. Packs from different suppliers vary in quantities so one either ignores the CE mark requirements or over or under supply; this alone makes the tender unworkable. No reply was forthcoming on this point raised in Clarification 4. In the Guidance on the Classification of Medical Devices issued in October 2021 incontinence products are listed as Class 1 medical devices.

Appellant confirms, continued Dr Paris, that no clarification was sought by it on the web application, but a bidder is not bound to seek a clarification before filing a Regulation 262 appeal. As confirmed in the *Truevo* judgement if a grievance exists it must be raised before participating in a call – there is no point at law that it is necessary to seek a clarification before requesting a remedy under this regulation. The technical offer does not request a web application. For a valid offer the technical form, which is a Note 3 document, has to cover all requirements and the Board is invited to confirm that all three technical offer forms do not mention that bidder has to provide web application. This creates future ambiguity and this is the whole point of appellant's objection. This could easily have been resolved through a clarification. The literature list is meant to corroborate the offer and is not a stand-alone document – the title itself indicates that and is meant to substantiate that the offer is compliant but is not the offer itself. Appellant's point is that once doubts have arisen on the matter of the web it would make sense to avoid any ambiguities. The impression has been given, and it has been so

stated, that this procedure has been undertaken to safeguard the position of the incumbent. This is not so; first of all, a Negotiated Procedure has been issued, secondly appellant is known for regularly requesting that any appeals are heard as soon as possible which belies allegations that appellant is trying to lengthen the process to benefit from it. Every economic operator is entitled to make use of Regulation 262 and it is certainly not a fact that the object of this exercise was to lengthen the process but an attempt to clarify what was unclear in the tender.

Dr Bezzina stated that the Contracting Authority maintains that the appeal must be clear and at least state under which regulations the appeal submitted. One cannot use a *carte blanche* and then expect the Board to decide under which regulation it is going to hear the appeal. There is no indication on which legal basis the appeal has been lodged and it still has not been indicated even at this stage. Regarding the injunction there was no definite decision on it by the Court and in any case this was withdrawn and has no bearing on this matter. The regulation 262 appeal by Pharma Cos was *fouri termine*. Up to the date of the injunction the time for filing an appeal had already passed – once this is exhausted it cannot be resurrected. If appellant was convinced that the tender had ambiguities logic should have pointed it to seek clarification. This point alone, and in itself, raises in one's mind the suspicion of a wish to lengthen the process. The request for information by the appellant (clause 1.3.4.1) seems to be an attempt to seek information which could easily have been sought through a clarification at an earlier stage.

Dr Bezzina further stated that the appellant has no right to dictate the terms of a tender and its apprehension and lack of ethics concerns on the quantity of units or packs was not evident or raised in the previous tender and it proceeded with the tender even though it was unethical. It is now claimed that the Authority's action is unethical when it seems to have been perfectly ethical for the appellant. Since different suppliers provide different sized packs then the common factor has to be the single loose unit otherwise it is uncompetitive and impossible to have a level common playing field. PCRB Case 1636 was cited as the perfect example of this when the Board decided that the common factor was a single sheet of paper. No proof was brought forward that the product is a medical device; Mr Fearne said that the CE mark on a product does not necessarily mean that it is a medical device and when asked he stated that the mark is no conclusive proof that the product is a medical device. There are guidelines but these are not binding.

According to Dr Bezzina the tender requested literature as part of the technical submissions and it was easy to be compliant by following the tender requirements. There were no barriers and it was possible to adhere to the requirements. The allegations by the appellant that the technical requirements were not clear were not proven with the witness called to testify on this point proving to be very unconvincing and it makes one wonder how convinced the Board on this point was. There is serious doubt on the existence of the organisations whose opinions were claimed to have been sought and on the reluctance to reveal their name. The failure to produce these so called specialist to testify means that the Board cannot rely on this testimony. Regarding the grievance on the licence this applies to all bidders and binds them all but in any case this is an *ex-post* factor.

Dr Inguanez said that the clarity of Regulation 262 gives different subsections to cover grounds for appeal and grievances must follow one of these. In truth none of the grievances raised in this appeal fall within the subsections of Regulation 262 and even when appellant quoted subclause (a) it failed to meet the requirements and was applied incorrectly. The economic operator is here trying to dictate the terms of the tender. In the Court of Appeal Case 834/2007/1 *GRTU vs Onor Prim Ministru* it was

held that the bidder cannot dictate the terms of acquisition. This is exactly what the bidder is trying to do in this case by its reference to BPQR etc. The Board is here to adjudicate on tender and not here to decide if the product is a medical device or not. As stated in Appeal 369/22/1 *Koperativa Ghawdxija* the Court held that the remedy of Regulation 262 cannot be used by prospective bidders to interfere in the drafting of a tender.
The Medical Authority, stated Dr Inguanez, said itself in evidence that it cannot define if the product is a medical device. Appellant is not claiming that he splitting of packs is unlawful but that it is matter for the authorities. The technical specifications on the web application are clear on this point.

Dr Debono said that every claim must relate to legal articles, something that is missing in this case. The claims on ambiguity and that the tender is unworkable have not been proven. The Contracting Authority is entitled to determine its own requirements and it is up to the economic operators to follow them. In Case 1228 the PCRB decided that the contracting authority has the right to decide its own acquisition requirements.

Dr Aquilina agreed that the single unit is the common denominator and appellant has been and still is, supplying as such and no regulations exist in stopping this practice. It must be borne in mind that the offer is not subject to a web application but to the price criteria.

Dr Mifsud Bonnici asked that the Board should decide on the preliminary points and the grievances as one. As regards the points made on the Regulation 262 application it is necessary to state the basis on which this is made as otherwise the Board has to guess. On the matter of the date of the reply the Board has already decided and this is a closed shop. This is a specific case and the Board has decided as such because it is a specific case. Appellant was never aware of the events.

Dr Calleja referred to exhibit 12 and went through a chronological timetable of the case and the date when certain events first became known. Case C-406/08 *Uniflex* was quoted in support of argument regarding date when infringement first became known and similarly Case C-98/14 *Berlington* and C-796/18 *IFC* that once the period of remedy expired all prospective candidates have legitimate expectation. Bidders should not take advantage of their own turpitude as appellant did not seek clarifications or remedy at that stage. Then came the injunction which created an extension in dates to enable the Regulation 262 remedy followed by a Negotiated Procedure also in favour of the incumbent. Finally, Dr Calleja made reference to Appeal 179/22/1 – economic operator cannot take advantage by illegal or abusive measures, and Appeal 2123/97/1 – a party should not benefit in case of *mala fides.*

Referring to the basis of the injunction, Dr Mifsud Bonnici said that the Court was misled that this was based on the lack of information but it failed to state that a clarification was available and had not been sought. Even then, appellant still had a period of two weeks in which information could have been sought. Procurement remedy states that if Regulation 262 rights have not been exercised that is the end of the story and the tender becomes a sealed box. The decree in Appeal 1372/2021 *Servizzi Malta vs LACC* was cited on the point that once Regulation 262 was not used any other remedies to stop the tender can be used. It is an abuse to use the Courts to stop the process to enable the filing of a 262 remedy. The decision in Appeal 873/20/1 *Barbarossa Excursions Ltd* was quoted in the context that if no precontractual remedy was sought then no further action can be taken by seeking a different route.

Dr Mifsud Bonnici stated that the Authority has the right to decide the format of a tender. On the question of the web software, it is clear that it had to be submitted at tender stage (clause 1.7.6). There is no legal argument in the procurement regulations that it should be removed. Krypton did not have to do anything in this case and it is simply stating the shortcomings of the other side.

Dr Paris, in his final comments, said that on the question of inadmissibility it should either all be decided or none otherwise the approach will be inconsistent. Ambiguity has been created in the tender requisites and specifications. There is no need to quote the articles of the law under which the appeal was raised – this has no basis and has been rejected in the past. It occasionally happen that the Board has cases which have not been appealed by a lawyer with no reference to points of law and it would be creating a dangerous precedent if it is established that appeals would only be heard if presented by a lawyer. For evaluation purposes it is right that the unit as a common denominator is used but the appellant's grievances are in the difficulty of executing the contract. The web application has to be limited to the technical offer form. Clarification Note 5 requested further information but this was never provided.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sittings of the 18th April 2024 and 6th June 2024.

Having noted the call for remedies filed by Pharma-Cos Limited (hereinafter referred to as the Appellant) on 31st January 2023, refers to the claims made by the same Appellant with regard to the tender of reference CT2238/2023 – Lot 1 listed as case No. 1996 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Paris
Appearing for the Contracting Authority:	Dr Noel Bezzina, Dr John Gauci & Dr Rachel Powell
Appearing for the Department of Contracts:	Dr Daniel Inguanez & Dr Mark Anthony Debono
Appearing for the Interest Party:	Dr Clement Mifsud Bonnici, Dr Calvin Calleja & Dr Krista Refalo

Whereby, the Appellant contends that:

a) ***1st grievance - Lack of predictability – ambiguity –***

The appellant company submits that, the tender document, as drafted, is in breach of article 38 of the PPR, and notwithstanding multiple clarifications, the tender document fails the ambiguity test, as follows: -

i) Quantities - Tender document versus reality

The tender document in provision 3.2 [page 4] indicates that, *The tenderer must offer the whole of the quantity or quantities indicated for each lot. Under no circumstances will tenders for part of the quantities required be taken into consideration. Each lot may form a separate contract and the quantities indicated for different lots will be indivisible'".* On its part, the Financial Offer (for all Lots) requests a unit price, as well as specific quantities. It is well known however that, the items requested in all lots, are delivered in packs and not in single units [loose nappies], and thus the execution of the contract as proposed is not feasible nor practicable. For clarities sake, whilst the contracting authority shall request the products in specific quantities, all economic operators are bound to supply in packs [and consequently charge for units which the end user is not be eligible for] - thus there is an impossibility to perform and thereby actions should be taken in accordance with article 262[1][a] of the PPR. For all intents and purposes, through clarification number 4 this matter was requested, however such question remained unanswered.

ii) Tender as proposed is in breach of the Guidance for Good Distribution - MA

The Medicines Authority has developed a 'Guidance for good distribution practice in relation to medical devices', wherein inter alia it clearly states that handling of medical devises shall be such which does not damage, tamper with, or in any manner deteriorates the packaging. The handling of units, as proposed in the tender [vide above] blatantly infringes the guidance documents of the Medicine's Authority, and as a consequence the packaging of the products that will be delivered to the end-users shall be de minimis deemed to be tampered with. In addition, whilst the tender document has requested conformity to the CE marking, the distribution in loose packs renders the CE marking redundant.

iii) Technical offer form not consistent with the tender specifications

The tender specifications, inter alia in specifications 1.2, and 1.6 to 1.7.6 requests an online web-based application, to supply the contracting authority with monthly updated lists for scheme 'A' and scheme 'B'. For some very odd reason, this is not however included within the tender technical offer form template provided, nor in any other technical offer - on the contrary all other tender specifications are included within the tender offer form. Whilst indeed mention of same is within the literature list, it is the tender offer which calibrates the offer by the economic operator, and the

literature is only there to corroborate that a technical offer is compliant - without the technical offer, the economic operator is not bound to supply the web-based application, nor can the contracting authority exclude an economic operator for its failure to offer the web application! As such, the tender document is requesting literature of a requisite which is non-existent in the tender specifications.

iv) Technical specifications for web application are ambiguous

The tender specifications for web application are ambiguous, as follows:

User Access: Sections 1.2 and 1.7.1 of the tender document describes what functionality is expected by the Contracting Authority, however it does not indicate how many users will require access to the system and to what extent. Please provide a specific list of the different user-types that will require access to the system, their expected permission levels, and the expected volume of users that will require access to the system throughout the course of the contract - taking into account any expected growth.

Lead Time for New Beneficiaries and/or Changes to the Beneficiary Product Prescription: Section 1.2 of the tender document states that the beneficiary data (including their product prescription, we assume) will be updated periodically by the Continence Nurse Advisors, in real-time by the web-application. Whilst the minimum buffer stock will be adhered to, the Contracting Authority understands that the Contractor cannot anticipate what changes will occur in the future, and thus, cannot have an unlimited supply of all the different products. Therefore, it is being assumed that a minimum lead time will be discussed and agreed upon with the Contracting Authority, to ensure that new requests or changes to the beneficiaries' product entitlement are handled within a specific timeframe, giving the Contractor a reasonable timeframe to address any necessary changes to the stock.

Manage Orders: Section 1.7.1 states that the system will automatically generate monthly product orders'. Is the Contracting Authority expecting the Contractor to have a fully automated order fulfilment process, with no interaction with the beneficiary? Please provide a step-by-step process indicating how beneficiaries will apply and receive their products, and how the system should interact during this process. Specifically, we need to understand what channels the beneficiaries will be expected to interact with (e.g. telephone/online form etc) and what resources the Contractor needs to allocate to support this process.

Managing requests to change the beneficiaries' product prescription: Given that changes to the product prescription need to be authorised by the Contracting Authority, can we assume that the beneficiaries must make such a request to the Contracting Authority directly and the Contractor will be notified about the changes through the web application?

Integration Capabilities: Given that the web application will be owned and administered by the Contractor, it is being assumed that no integrations to the Governments systems are required, and any and all integrations that may be required by the Contractor shall be handled directly at his/her discretion so long as the supply/deliver processes are respected.

Demo: In order to provide a demo for the tender process, the Contractor will be required to invest in additional licences and professional service fees. Please clarify (a) that the demo does not need to represent the entirety of the solution (as this would require the actual setup and configuration of the end solution before the tender is actually awarded) and (b) that one user license will suffice for a period of two (2) months for the tender evaluation purposes

In view of the aforesaid and without prejudice to provision 1.3.3, de minims, the contracting authority must issue clarification notes to address the ambiguities herein defined. In addition to the aforesaid, it is the opinion of the appellant company that the price for the web application should be separate from the price of the lots service requested.

b) ***2nd grievance - Award criteria - ensuring the effective competition***

The tender document in provision 6, stipulates that the sole criteria for award shall be "the price ... satisfying the administrative and technical criteria";

Whilst indeed permissible, it is the position of the appellant company, that the award criteria is not appropriate in the circumstances, and it would be more appropriate to have a best price quality ratio [BPQR] award criteria. In the procurement under review, one of the main characteristics of the diapers is the absorption capacity - so much so that, the Contracting Authority developed a minimum absorption capacity [vide tender document pages 26 to 33]. It is the position of the appellant company that, for the Contracting Authority to purchase the most economically advantageous offer, without distorting effective competition, it is to change the award criteria from a price only to a BPQR, award criteria. This would ensure that wheresoever a product offered is of a better quality, it is given a better rating as opposed to the ones that merely satisfy the requirement.

c) ***3rd grievance - Identical products - Inconsistent procurement procedures -***

The subject matter of this tender is also the subject of two [2] other pending procurement, namely SPD 3/2022/045; MGOZ NP 02/2023; - all of which are pending appeals before this Honourable Board. Whilst all procurement procedures are distinct from each other, consistency in the procurement of identical products is fundamental, to ascertain that the principles of proportionality and transparency are safeguarded.

d) ***Other matters -***

i. It is to be pointed out that the Contracting Authority is failing to understand that this tender is for the provision of service and not for the supply of a product, and thereby this procurement is to be treated as such.

ii. Additionally, the tender fails in addressing operational issues in relation to distribution, including but not limited to there is no turnaround time from date of order to date of supply.

iii. Additionally, the tender fails in addressing operational issues in relation to distribution, including but not limited there are no service level objectives to ascertain that the service offered by the awarded bidder is in accordance with the required standards.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 25th October 2023 and its verbal submission during the hearings held on 18th April 2024 and 6th June 2024, in that:

a) ***1st grievance - Lack of predictability – ambiguity –***

i. Tender Document vs reality

In this regard, the Contracting Authority hereby submits that, the Appellant is incorrect in saying that the requirements of the tender document will make it impossible for the bidders to perform and by extension comply with the tender requirements. It is evident from the wording used in the tender document itself, that what the CA is actually requesting is a minimum quantity to be supplied by the tenderer. At no stage or part of the tender document did the CA require that specific quantities are to be supplied, but it merely established a minimum quantity which could easily be met by the tenderer. Indeed, the appellant's argument is fallacious since if the minimum quantity required in the tender document is met, then such tenderer would be compliant irrespective of whether such products are delivered in single units or packs.

ii. Tender in breach of the Guidance for Good Distribution

The argument submitted by the CA above renders the appellant's argument on this issue moot and redundant, since as already stated, a tenderer may submit an offer of a quantity of packs (as opposed to units) and still be compliant with the tender requirement. Additionally, and without prejudice to the above, the Guidance for good distribution practice in relation to medical devices does to incorporate or refer to incontinence products. As a matter of fact, the very definition of 'medical devices' provided by the document excludes any reference to incontinence products and consequently, such items are not deemed as medical devices.

iii. Technical offer form not consistent with the tender specifications.

At the outset, it is pertinent to clarify that this tender was issued for the provision, supply and distribution of incontinence products. Therefore, and rightly so, the requirements of the technical

offer form are only limited to the provision of such incontinence products. That being said, the tender document indeed required the provision of an on-line web based application. Contrary to what is being argued by the appellant, a tenderer is still deemed to be compliant with this requirement if in his submission, particularly the technical literature, the tenderer includes the provision of a web-based application. In fact, the evaluation committee may still determine whether a tenderer is compliant with this requirement if and once a web-based application is provided as required in the tender requirements. If no such web-based application is included, then naturally the tenderer would be disqualified. Additionally, once in substance, the technical literature submitted is in compliance with this requirement, then if follows that a tenderer may indeed be compliant.

iv. Technical Specifications for web application are ambiguous.

The Contracting Authority submits that the requirements and the technical specifications with respect to the web application are clear and sufficient for all bidders to submit their offers and be in compliance with same requirements.

b) ***2nd grievance - Award Criteria - ensuring effective competition -***

With respect to this ground of appeal, the Contracting Authority humbly submits that such ground cannot be entertained by this honourable tribunal since it is not contemplated as one of the specific circumstances contemplated in Regulation 262 of the PPR. Additionally, and without prejudice to the above, as evident from the tender document itself and as already stated in this reply, the tender was issued for the provision, delivery and distribution of incontinence products. The tender also prescribed minimum requirements which the bidders were to satisfy. Therefore, all bidders who meet the minimum requirements, be it in terms of quantity and/or quality, then such will be compliant with the tender requirements. In such circumstance, the award criterion chosen in the tender document (price only) is sufficient for the purposes of this tender.

c) ***3rd grievance - Identical products - Inconsistent procurement procedures -***

The appellant argues among other things, that *" the same matter and the same clauses have been modified on a number of occasions, thus creating uncertainty and vagueness"*. With all due respect, as the appellant himself states, such tender procedures are currently pending proceedings (sub judice) and one cannot definitively conclude that such tenders are creating uncertainty and vagueness. In the absence of definitive decisions by the PCRB or the Court of Appeal, such conclusions by the appellant cannot be made. Also, the Contracting Authority submits that the merits of each of the tender procedure quoted, besides the present one, do not form part and have nothing to do with the merits of the present appeal. Moreover, it is up to the department issuing the tender document to structure the tender document in a manner which would suit its needs and at the same time following the PPR and legal principles.

This Board also noted the Department of Contract's Reasoned Letter of Reply filed on 25th October 2023 and its verbal submission during the hearings held on 18th April 2024 and 6th June 2024, in that:

a) ***Inadmissibility of claims (ii)-(x) [reference to paragraph 1.1. of reasoned letter of reply]***

Pharma-Cos raises a total of ten (10) claims in its application. Pharma-Cos makes no attempt to identify, for each of its claim, one of the five (5) grounds for which the remedy before closing date of a call for competition may be invoked according to Reg. 262(1) of the Public Procurement Regulations.

It is only with respect to its first claim (Quantities - Tender document versus reality) that the application specifically identifies the ground for appealing - that is, Reg. 262(a). For the rest of the nine (9) claims no legal ground is cited. The Director of Contracts submits that this on its own is sufficient for this Honourable Board to declare the application in admissible with respect to claims (ii)-(x). It is neither the role of this Honourable Board nor that of the Contracting Authorities to try to elucidate what the applicant's claims are. Even so, and without prejudice to the above, the claims (ii)-(x) of Pharma-Cos are inadmissible because they do not fall within any of the grounds of Reg. 262(1)(a)-(e). It would appear that this is why Pharma-Cos fails to ground these claims on any provision of law; precisely because there is no legal basis to put forward such claims.

b) ***Claim (ii) - that the procurement of the supplies in units rather than pack is in breach of the Guidance for Good Distribution issued by the Medicines Authority: -***

It is not for Pharma-Cos to decide whether the call for tenders must strictly abide by the *Guidance for good distribution practice in relation to medical devices*, which is in any case simply 'guidance' and not a binding document. Whether the call for tenders conforms strictly to that guidance does not affect the prospective tenderer's interests or rights; it is simply a matter of internal administration to decide whether to comply with that Guidance or not.

c) ***Claim (iii) - that the technical offer forms are inconsistent with Art. 1.2. 1.6 and 1.7 of the Technical Specifications:***

Pharma-Cos contends that since the technical offer forms do make any mention of the online web-based application that is requested inter alia in Art. 1.2, 1.6 and 1.7 of the Technical Specifications, then, there is an inconsistency. Firstly, this suggestion is ludicrous since the requirements for a web-based application are clearly stated in Art. 1.2, 1.6 and 1.7 of the Technical Specifications and specific literature has been requested in the Technical Offer Forms. Secondly, it is not for the prospective bidder to decide how the authorities draft their call for tenders; and for good reason, since the applicant is evidently under the mistaken assumption that the Technical Specifications and the Literature List do not form part of the. The conditions relating to the web-based application apply to all bidders and the call for tenders has been issued under the responsibility of the respective authorities, nowhere does Reg. 262 entitle Pharma-Cos to intervene in the drafting of the Technical Offer Forms.

d) ***Claim (iv) - that the authorities must issue clarification notes on the Technical Specifications relating to the web application (Art. 1.2 and 1.7.1) and that the price for the web application should be separate from the price of the supplies requested-***

Under this claim Pharma-Cos effectively submits questions for clarifications under Reg. 38(2) of the Public Procurement Regulations, even though the Clarification Period ended on the 29th September 2023. It is quite suspicious that its questions only arise now. It is even more suspicious considering that Pharma-Cos is the incumbent contractor. Even so, Art. 1.7 of the Technical Specifications are sufficiently comprehensive. The arguments made by Pharma-Cos are rather intended to tweak the final contract conditions as it sees fit. Again, the Technical Specifications apply to all bidders, it is not for any prospective candidate to dictate how the web-application should function or even to give its opinion on what the technical specifications should be. As for its suggestion that the price for the web application should be separate, again, the fact that the web application must be offered together with the supplies procured is a discretionary decision of the contracting authority which is not subject to review by this Honourable Board according to Reg. 262.

e) ***Claim (v) - that the contracts should be awarded on the basis of the best price-quality ratio (BPQR) instead of the cheapest price: -***

Once again, Reg. 262 does not entitle prospective tenderers to draft the call for tenders themselves or to decide on how the contracting authority should make its acquisitions. The use of one award criterion instead of another is at the sole discretion of the contracting authority. The award criterion applies to all tenderers and does not affect the interests and/or rights of the Pharma-Cos.

f) ***Claim (vi) - that different contracting authorities should not use different procurement procedures for the procurement of the same supplies (with specific reference to call for tenders SPD3/2022/045 and MGOZ. NP 02/2023):***

Again, if Reg. 262 does not entitle prospective tenderers to decide themselves on how to organise the procurement procedure it definitely does not entitle them to force different contracting authorities to adopt the same procurement practices. The different procurement procedures are open to all interested economic operators under the same conditions, the fact that different procedures/contracting authorities use different methods does not affect the interests and/or rights of the Pharma-Cos.

g) ***Claim (vii) - that the tender is one for services not one for supplies:***

The tender is issued by the contracting authority. It is its discretion to decide on what it needs to buy. In this case it has used its discretion to procure supplies not services. It is definitely not the case that "the Contracting Authority is failing to understand that this tender is for the provision of service and not for the supply of a product". It is rather Pharma-Cos which is failing to understand its place in this procurement procedure.

h) ***Claim (viii) that there should be a turnaround time from date of order to date of supply:***

Pharma-Cos attempts here to change not only the tendering criteria but the conditions of the contract to be finally awarded. As has stated in the last preceding point, it is not for any prospective tenderer to decide what the contracting authority needs to buy. Additionally, the current call for tenders is not a procedure with negotiation. Should Pharma-Cos dislike the contract conditions it remains free not to submit an offer.

i) ***Claim (ix) there should be service level objectives to ascertain that the service offered by the contractor is in accordance with required standards:***

The preceding comment applies also here. The alleged absence of service level objectives applies to all tenderers and in no way does it affect the interests and/or rights of the Pharma-Cos.

j) ***Claim (x) that the call for tenders should request a licence for the distribution of medical devices:***

Firstly, the suggestion of Pharma-Cos is irresponsibly given and ill-thought out. The supplies to be procurement by the present call for tenders do not even seem to fall under the definition of "medical device" under the Medical Devices Regulation (2017/45). In any case, if an economic operator has obligations derived from law in the conduct of its business, such as having the necessary licences to conduct the business, then, a call for tenders need not necessarily request those same obligations. If there is a legal requirement for the distribution of incontinence products to be covered by a licence, then, the contractor must continue to abide by the law irrespective of whether the call for tenders has reproduced legal requirements. As such, the absence of any licensing requirement in the tender applies to all tenderers indiscriminately and does not affect the interests or rights of Pharma-Cos. If, outside of the call for tenders, there is a legal requirement to be licensed then such legal requirement also applies to all tenderers.

k) ***Claim (i) is unfounded***

Turning now to the only claim that has been framed within one of the grounds of Reg. 262, that is, sub-regulation (a): *to set aside or ensure the setting aside of decisions including clauses contained in the procurement document and clarification notes taken unlawfully at this stage or which are proven to be impossible to perform.*. Pharma-Cos claims that there is an impossibility to perform the contract since the price is quoted in units but the economic operators are bound to supply in packs.. The call for tenders clearly requests specific quantities of each items and Clarification Note 4 confirms that the contractor must make available the quantities needed. There is no impediment for the eventually chosen contractor to supply quantities even if the contractor himself acquires the items in packs.

This Board also noted the Interested Party's Reasoned Letter of Reply filed on 30th October 2023 and its verbal submission during the hearings held on 18th April 2024 and 6th June 2024, in that:

a) ***Preliminary Pleas: The Appellant's application is inadmissible because, as a fundamental principle of Maltese law, no appellant should be allowed to gain an advantage through its own abusive behaviour and, in any case, the right of action is extinguished. -***

The Appellant's conduct, including the content of this application itself, is purportedly and overtly to rewrite certain aspects of the tender. As both the Department of Contracts and the Contracting Authority plead in their replies, the Appellant has no right to insist that certain tender clauses are written in a certain way 'just because'. This is not the purpose of Regulation 262 of the PPR, which is intended to serve one of six limited circumstances envisaged in paragraphs (a) to (e) of that Regulation. As the Department of Contracts and the Contracting Authority contend, the claims raised by the Appellant do not attempt to achieve any one of the six goals for which Regulation 262 of the PPR was created. Rather, the Appellant sets out a substantial amount of suggested improvements to the tender document: no less than ten suggestions have been put forward in its application. None of the claims put forward were ever raised by the Appellant prior to this application by means of clarification requests. The only exception is the first claim on the alleged impossibility of supplying the product in quantities rather than in packs which formed the subject-matter of a clarification published by the Contracting Authority on 14 September 2023. The Appellant only deemed fit to raise these grievances in respect to the Tender at this stage, having failed, either deliberately or out of negligence (although the Appellant is no stranger to procurement proceedings), to exercise its right to request clarifications earlier or to file this application earlier within the limitation period provided for at law.

The Interested Party submits that the deadline for the filing of the application in terms of Regulation 262 of the PPR had already lapsed when the Appellant obtained the issue of the Injunction. Therefore, and by application of the general principles of EU and Maltese law of legal certainty and legitimate expectations, that right of action was extinguished. The Appellant must be arguing that its right of action was "revived" when the Department of Contracts, in reaction to the Injunction-which was provisionally upheld by the Court, suspended the Tender and extended the closing date until the Court decides the Injunction on a definitive basis. The Appellant frantically withdrew its hopeless Injunction and immediately filed this present application. This is unprecedented skullduggery which should NOT be tolerated by any judicial body. The Appellant cynically abused of its extraordinary remedies in civil procedural law to re-open a door that was closed shut and which it elected not to pass through when it was wide open for *"the first two-thirds of the time period allocated in the call for competition for the submission of offers"*. Substantively, the Department of Contracts did not extend the closing date of submissions, but suspended the Tender due to the Injunction. It is a known fact that the suspension of a Tender is not possible on ePPS, and therefore, the Department of Contracts customarily extends the closing date to achieve this objective. This does not mean that, as a consequence of the suspension of the Tender caused by the Injunction, the Appellant's right of action in terms of Regulation 262 of the PPR was "revived".

Further, and given that the right of action in terms Regulation 262 of the PPR had extinguished, the other economic operators have acquired "legal certainty" and "legitimated expectations" which will be expropriated by this Honourable Board if this application is considered.

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.

a) ***On the inadmissibility of claim (ii)-(x) as raised by the Department of Contracts -***

i. Reference is made to Regulation 262(1) of the Public Procurement Regulations ("PPR"). The Board will make two separate and distinct observations about this Regulation.

ii. Initially, this Board agrees with arguments as brought forward by the appellant, in that the wording used by the legislator in reference to Regulation 262(1) is somewhat different to that used for Regulation 270. In Regulation 270, the law is very specific in demanding 'very clear reasons for the complaints'. This 'wording' is however missing from Regulation 262(1).

iii. Secondly, while Regulation 262(1) does not make reference to such a requirement as mentioned above, it then goes on to list five (5) specific instances whereby a prospective candidate may file a reasoned application before this Board. Therefore, it goes without saying that grievances should fall specifically / strictly within the purview of sub-articles 261(1)(a) to 261(1)(e).

iv. Whilst noting that the appellant 'cross referenced' only one of his grievances in this manner, this Board can now only try to interpret the appellant's grievances according to its own analysis. In conclusion, while this Board will none-the-less proceed to pronounce itself on all of the grievances as filed by the appellant, it stands to reason that this is either an oversight which went amiss or else a conscious attempt to mislead. Therefore, it cannot be said that this Board has not correctly interpreted the grievances, once it was the same appellant who fell short in this instance. Important to note, that not even in the oral submissions did the appellant try to perform this 'cross referencing' exercise.

b) ***On Krypton Chemists Ltd's reply, filed on 30th October 2023, being fuori termine –***

i. The Board refers to the interlocutory decision delivered verbally during the first hearing held on 18th April 2024. Within such decision it was concluded that the request of the appellant should not be granted. This in view of the specific and exceptional circumstances peculiar to this case. Moreover, the Board is serene in taking this decision and that this will not constitute a precedent once the Department of Contracts has taken steps to address and update the ePPS system which created such an issue. Therefore, such instances will not be re-occurring in the future.

c) ***On the Preliminary plea as submitted by the Interested Party (Krypton Chemists Ltd) -***

i. As from the outset, this Board will only deal and decide on what it deems strictly relevant to it. This to ensure that its final decision would not be *ultra vires*.

ii. Again, these are peculiar conditions whereby this Board will not be adding here to what has already been decreed in its interlocutory decision, especially ones the 'flaw' within the ePPS has already been amended by the Department of Contracts. From now onwards, if a similar situation occurs, the tenders process will be 'suspended' rather than 'extended'.

iii. Once in this specific situation, the period was 'extended', this Board will continue with hearing the grievances as raised by the appellant.

iv. The Board reaffirms its position that the decision taken *a tempo vergine*, will not constitute a precedent in the future given that the ePPS 'flaw' has now been rectified.

d) ***On the issue of Medical devices -***

i. Reference is made to the testimony under oath of Mr Julian Fearne. It must be stated that when one considers the current position held by Mr Fearne as Senior Head 'Medical Devices' within the Medicines Authority as well as currently reading for a Ph.D in Medical Devices, he is more than an authoritative figure on the subject matter.

ii. During his testimony he stated that:

A. *"incontinence products is a very vast subject and it was up to the manufacturer to declare if the product was a medical device, although the definition of a medical product is in the legislation"*

B. *"The items listed in the tender could be either medical devices or not"*

C. *"the majority of items could mainly be considered as medical devices with the greater possibility being that the inco sheets are medical devices – the other products depend on how they are classified by the manufacturer"*

D. *"the guides are not legally binding"*

iii. Once no conclusive evidence was presented before this Board, and not even the expert witness could categorically confirm if the items being procured in this tender process are in fact 'Medical Devices', this Board cannot certainly confirm if the tender as proposed is in breach of the Guidance for Good Distribution as issued by the Medicines Authority.

iv. Once it was 'up to the manufacturer to declare if the product was a medical device' or otherwise, this Board opines that it was incumbent on the appellant to present irrefutable and independent evidence that such items are in fact classified as 'Medical Devices'. Once this has not been done, this Board cannot uphold the appellant's grievance.

e) ***On the issue of units rather than packs –***

i. Once it has not been confirmed that the products being procured fall strictly under the definition of 'Medical Devices', this Board finds no ambiguity in the Financial Bid Form requesting economic operators to submit a 'Unit Price'.

ii. A Financial Bid Form requesting a 'Unit Price' will achieve a same level playing field between operators. This is more so the case when 'packs' of different economic operators might differ in the number of units held within them. This same issue was discussed and decided upon in PCRB Case 1636 which in turn referenced PCRB Case 1017 whereby it was stated that **"***This Board after having examined the Tender Document and other relevant documentation, opines that it is not its jurisdiction to delve into the mathematical calculation of the price. However, it would like to respectfully treat the merits of the issue of "Price per Roll" as dictated in the Tender Document. It is vividly clear that the latter requested a quote for the supply of kitchen rolls and the award criteria was the price, so that the award rested on the cheapest fully compliant offer. At the same instance, this Board justifiably notes that the "Rolls" quoted for by Bidders did not contain the same volume or quantities of sheets and in this regard, the Evaluation Board had to evaluate the costs on a Level Playing Field. This Board opines that a common factor had to be established to determine and compare the offers on equal footing and in this regard, this Board notes that the only available factor on which the Evaluation Board could compare these offers with regards to the price, was the number of sheets in each roll. Only this basic factor could determine which is the cheapest offer. This Board also contends that the Central Procurement and Supplies Unit's main intention was to obtain the supplies within the specifications, as dictated in the Tender Document, yet at the cheapest possible price. It is a fact that this Board's parameters are restricted to the determination of whether the Evaluation Board had excersided a fair and equal treatment to all Bidders. However, this same Board cannot ignore the fact that, since the Award Criteria was the price, and the "Rolls" submitted by Bidders did not contain the same volume of sheets, the price had to be based on a common factor which would eventually allow the Evaluation Board to treat the adjudication for the same unit of supply throughout. In this particular instance, this Board opines that although the Tender dictated a price per roll and the rolls submitted contained variable columns of sheets, the common factor to establish the cheapest quote was a "Rate per Sheet" contained in each particular roll."*

f) ***On the Technical offer form not being consistent with the tender specifications -***

i. The tender document is very clear and unambiguous in paragraphs 1.2, 1.6 – 1.7.6 that an online web-based application is required as part of a submission by any economic operator. This is being requested for the good and proper management of the products and services being provided by the Contracting Authority to its eventual end users.

ii. It goes to follow that in order for these specifications to be legally binding, especially during the live term of this tender (reference to paragraph 1.2 of Section 1 of the Tender document), that a clarification notice is issued by the Contracting Authority to amend the Technical Offer Form to include a self-declaration that the economic operator will be duly complying with these particular specifications of the tender document. Such clarification note should make it amply clear that this 'new' Technical Offer Form will supersede the 'old' form as originally published in the tender document.

g) ***On the Web application – Technical Specifications being ambiguous -***

iii. Reference is made to the testimony under oath of Mr Gordon Zammit whereby numerous points were raised.

iv. However, initially, this Board cannot fathom as to why all these issues were never raised by the appellant by way of clarification before this call for remedies. Whilst it is also true that there is no obligation that an economic operator has to submit a clarification request addressed to the Contracting Authority before being allowed to file a 'Remedies before Closing date of a Call for Competition', it is only natural and in the interest of 'expediency' that such issues are tackled in the most efficient manner.

v. Most importantly, reference is now made to when the witness could not remember the names of the firm/s he contacted regarding the web application. It could have been more opportune for the appellant to provide evidence in the form of the actual IT expert/s utilised confirming incompatibility of service with the specification listed in the tender document.

vi. The proof as presented by the appellant, mainly in the form of the testimony of Mr Gordon Zammit is nothing more than *detto del detto* and therefore what the witness referred to in his testimony, when the appellant also failed to produce that IT expert as a witness, constitutes nothing but hearsay evidence which is entirely inadmissible before this Board.

h) ***On the Award criteria – BPQR -***

vii. After thorough analysis, this Board concludes that this grievance cannot be 'cross-referenced' to any of the sub-articles 261(1)(a) to 261(1)(e). Therefore, such a grievance cannot be considered any further. This Board is constituted as per specific regulations of the PPR to decide on grievances filed before it, and not to comment on 'suggestions' as filed or submitted by appellants.

i) ***On the issue that the tender is one for services not one for supplies –***

i. After thorough analysis, this Board concludes that this grievance cannot be 'cross-referenced' to any of the sub-articles 261(1)(a) to 261(1)(e). Before declaring that such a grievance cannot therefore be considered any further, this Board would also comment that the appellant has not substantiated such comment and that this claim is somewhat superfluous once the same appellant is claiming that products to be supplied as per this tender procedure would also fall under the definition of 'Medical Devices'.

j) ***On the turnaround time from date of order to date of supply -***

i. After thorough analysis, this Board concludes that this grievance cannot be 'cross-referenced' to any of the sub-articles 261(1)(a) to 261(1)(e). Possibly it could be somewhat associated with Regulation 262(1)(c), however, this is just a presupposition on behalf of the Board. Once the appellant fails to specify how this issue raises a form of 'discriminatory technical specification', this Board concludes that this grievance cannot be considered any further.

k) ***On the service level objectives (required standards) -***

i. After thorough analysis, this Board concludes that this grievance cannot be 'cross-referenced' to any of the sub-articles 261(1)(a) to 261(1)(e). Possibly it could be somewhat associated with Regulation 262(1)(c), however, this is just a presupposition on behalf of the Board. Once the appellant fails to specify and proof how this issue raises a form of 'discriminatory technical specification', this Board concludes that this grievance cannot be considered any further.

l) ***On the licence for the distribution of medical devices -***

i. This grievance / comment of the appellant intrinsically falls parallel to the grievance that the products being purchased should be defined as a 'Medical Device'. Once it has already been concluded that no final and conclusive proof was provided that the products being procured are in fact 'Medical Devices', this grievance becomes moot and this Board cannot consider it any further.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides in relation to Lot 1:

a) Not to uphold the Appellant's concerns and grievances except for the claim entitled *"Technical offer form not being consistent with the tender specifications"*

b) To order the contracting authority to issue a clarification note in relation to the Technical Offer Form in line with the considerations and findings of this Board;

c) To amend the 'Closing Date of the Call for Tenders' as necessary whilst also taking into consideration the timeframes of Regulation 284;

d) after taking all due consideration of the circumstances and outcome of this Call for Remedies, directs that one tenth (1/10) of the deposit be refunded to the Appellant.

Mr Kenneth Swain	**Mr Lawrence Ancilleri**	**Dr Vincent Micallef**
Chairman	**Member**	**Member**