PUBLIC CONTRACTS REVIEW BOARD

Case 1843 – CT 2095/2022 – Tender Supplies – Fluorodeoxyglucose F – 18 Injections

27th April 2023

The tender was issued on the 11th May 2022 and the closing date was the 31st May 2022. The estimated value of the tender excluding VAT, was € 730,000.

On the 28th November 2022 Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their offer was deemed not to be the cheapest priced offer satisfying the administrative and technical criteria.

A deposit of € 3,650 was paid.

There were four (4) bids.

On the 26th January 2023 the Public Contracts Review Board composed of Mr Lawrence Ancilleri as Chairman, Dr Vincent Micallef and Mr Richard Matrenza as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Dr Francis Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Mr Jefferson Galea	Chairperson Evaluation Committee
Ms Federica Spiteri Maempel	Secretary Evaluation Committee
Ms Kathryn Galea	Evaluator
Ms Sara Bonavia	Representative
Dr Alison Anastasi	Representative

Preferred Bidder – JV Healthcare Ltd

Dr Norval Desira	Legal Representative
Dr Nicholas Grima	Representative
Ms Alexandra Rossignaud	Representative

Department of Contracts

Dr Mark Anthony Debono Legal Representative

Mr Lawrence Ancilleri Acting Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Matthew Paris Legal Representative for Cherubino Ltd requested that witnesses be heard before submissions.

Mr Jefferson Galea (413076M) called as a witness by the Appellant testified on oath that he was the Chairperson of the Evaluation Committee (EC) and detailed the composition of the Committee which was composed differently to the previous EC. According to the witness there were no clarifications sought, no requests for additional information and the EC relied entirely on the submissions filed in the previous evaluation. The PCRB decision in Case No 1772 was followed. Witness confirmed Appellant's reply to specification 3.8 in the Technical Offer Form.

Ms Kathryn Galea (162098M) called to testify by the Appellant stated on oath that the EC had followed the PCRB decision entirely and accordingly had evaluated all bids. Part (b) of the decision had not been part of their remit.

In reply to a question from Dr Norval Desira, Legal Representative for JV Healthcare Ltd witness confirmed that the EC had re-evaluated all bids.

This concluded the testimonies.

Dr Paris in his submission stated that Cherubino had bid with three separate products and had been failed on all three. This appeal, however was on only one bid, based on the Italian product. The original appeal on this was decided in Case 1772 – since then there has been the time factor and the possibility of obtaining registration of the product. It has been established in specification 3.8 in the technical offer form Appellant declared something not in line with the facts – the declaration was mismatched and this was accepted by the PCRB in their points (b) and (c) in Case 1772. There was no appeal on this decision and therefore the matter has been rendered *res judicata.* The decision is final in accordance with PPR Article 93 (5). The PCRB has judicial powers and once no further action was taken on their decision there was no right on the part of the CPSU to appeal and the Board's decision has to be adhered to and cannot be reversed. JV Healthcare should have been excluded on the basis of that decision.

Dr Desira said that the PCRB never stated that JV Healthcare should be disqualified and therefore it was right that their offer should be re-evaluated. It was established that the registration of the product was in Turkey and it is claimed that in the technical offer of Appellant a mismatching answer was given. Turkey is part of Europe and competent to register a product. One of Cherubino's products offered originated in Turkey.

Dr Leon Camilleri Legal Representative for the CPSU said that the role of the Board is to ensure correct evaluation and their decision was to have the tender re-evaluated with a fresh EC. Any decision is subject to appeal. JV Healthcare had a right to have their bid re-evaluated and this

defeats the claim that the matter was *res judicata.* The PCRB powers in the matter *of res judicata* are limited. Once there is a new decision then the full process of revising it must take place.

Dr Mark Anthony Debono Legal Representative for the Department of Contracts stated that the Department agrees with the arguments made by the CPSU – once a tender is re-evaluated a new process starts.

After a short discussions between the legal representatives regarding basis on which *res judicata* claims were made the Chairman proposed a short recess for the Board to consider the points made.

On resumption the Chairman said that the Board does not accept the argument that the matter is *res judicata* and will proceed with hearing the case on its merits.

Dr Paris said that he accepts the decision of the Board. In view of the fact that the circumstances regarding the registration of the product are the same, and that the product lacks registration in Europe by a competent authority, then he would request that the evidence produced in case 1772 relating to the same tender should form part of his submissions in this case.

Dr Desira noted that no transcript of that case was available to parties, and as his client was not legally represented at that first hearing, it would be prejudiced. Consequently he requested that it is formally noted that:

"Since JV Healthcare were not assisted by a lawyer in previous proceedings nor is their representative Damien Stellini present for these proceedings Dr Desira contends that the evidence on the present appeal from a new evaluation procedure should be limited to such a new evaluation procedure as this would otherwise be prejudicial to their proper defence."

The Chairman stated that following the submissions by Appellant and the Preferred Bidder the decision of the Board is that this hearing is adjourned to the 16th March 2023 at 9.00am with the direction that all parties concerned are to summon their respective witnesses to be heard at this adjourned session. He then declared the hearing adjourned.

End of Minutes.

SECOND HEARING

On the 16th March 2023 the Public Contracts Review Board composed of Mr Lawrence Ancilleri as Chairman, Dr Vincent Micallef and Mr Richard Matrenza as members convened a public hearing to further consider this appeal.

The attendance for this public meeting was as follows:

Appellant – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Dr Francis Cherubino	Representative (online)

Mr David Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Federica Spiteri Maempel	Secretary Evaluation Committee (online)
Ms Kathryn Galea	Evaluator (online)
Dr Alison Anastasi	Representative

Preferred Bidder – JV Healthcare Ltd

Dr Norval Desira	Legal Representative
Dr Nicholas Grima	Representative
Mr Damien Stellini	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative

Malta Medicines Authority

Dr Jessica Zarb	Representative
Dr Sonia Consiglio	Representative

Mr Lawrence Ancilleri Acting Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Matthew Paris Legal Representative for Cherubino Ltd requested that witnesses be heard first.

Ms Kathryn Galea (162089M) called to testify by the Appellant stated on oath that she was the sole evaluator in this tender apart from the Chairperson and Secretary. Out of the four offers received two bids were selected for final evaluation as they satisfied the technical specifications. JV Healthcare (JVH) replied to a clarification on the first evaluation and their offer was eligible. The clarification sought was regarding the enrolment in the professional register of a member state. The second compliant bid was submitted by Cherubino Ltd (Bid 000174931). Two other bids by Cherubino were disqualified – one of these bids (000174932) offered a product originating from Turkey and requested the use of Article 20 in the tender to be applied. The winning bid by JVH offered the product Moltek FDG Solution originating and registered in Turkey.

According to the witness, JVH confirmed in Clause 3.8 of the technical offer form that the product was produced in Europe. The failed offer by Cherubino was disqualified since it imposed a condition. Witness stated that a competent authority in Europe is any medicines authority in any EU state. Registration was not requested from JVH as this was not a matter in the hands of the evaluators. In Clause 3.8 JVH stated that registration was already in hand.

In reply to a question from Dr Leon Camilleri Legal Representative for the CPSU witness stated that she is a pharmacist by profession.

Questioned by Dr Norval Desira the Legal Representative for JVH witness said that she was not involved in the drafting of the tender. With reference to Clause 3.8 she confirmed that the word used was 'Europe' not 'EU'. Fluorodeoxyglucose (FDG) is a medicinal product licenced to trade in Europe. With regard to Clause 9.11 in the tender witness agreed that one can use the 90 days' time limit or apply for authorisation under Article 20 of the Medicines Act – this was following the instructions given to the evaluators.

Replying to Dr Paris witness stated that Registration No 2014/346 was the market registration for Moltek and that no document was submitted indicating that JVH were relying on Moltek's registration.

A further question from Dr Desira elicited the reply from witness that the evaluators ensure that a product is licenced in line with specifications and requirements.

Ms Helen Vella (77367M) called to testify by the Appellant stated on oath that she is the Director of Licencing at the Medicines Authority and that there are four (4) FDG products registered for trading in Malta. A product has to be registered in an EU member state to trade in Malta. The process of registration is normally applied for by others to obtain marketing authorisation – that could be EMA or nationally for a particular country. In the case of a Turkish product the applicant has to be from an EU country – the process is regulated by the EU and has to be completed in 210 days maximum. Witness confirmed the registration of four (4) companies as listed in document exhibited by Appellant. If a product is already authorised in the EU then it is possible to issue local authorisation under Article 126A whilst Article 20 of the Medicines Act authorises product registration for a short time if there is no alternative and it is necessary on public health needs. There was a previous exemption for Moltek.

In reply to questions from Dr Desira witness confirmed that it was the Superintendent of Public Health that is the ultimate authority on applications for registration. The request for the 126A registration was not from JVH but form the CPSU due to a matter of urgency. Witness stated that she was not involved in the tender process and was not aware if the product is already in use in Malta although this was irrelevant to a market authorisation process. She confirmed that JVH was authorised to trade in medicinals. Holding an GMP certificate does not mean a product is registered but is proof of good practice. According to the EU Directive applicant has to be registered in the EU either by the EMA or the Malta Authority.

In reply to a question from Dr Paris witness re-iterated that the GMP is a certificate of good practice in manufacturing. The Medical Authority recognises authorisation in EU states.

Dr Alison Anastasi (398380M) called to testify by JVH the preferred bidder stated on oath that she has been the Head of Operations Procurement at CPSU since 2018. She explained the use and purpose of FDG and said that it has a very short shelf-life – a matter of a few hours. She is familiar with the product Moltek since due to urgent requirements the product is already in use in the hospital. There were issues with the previous supplier of FDG (Cherubino) in 2021 due to failure to supply on time with a subsequent Court case and the Authority could not proceed with the contract. The provision of FDG because of its nature requires a near source of supply with nearby flights. Article 20 was used to allow the importation of the Moltek product which proved to be as efficacious as the previous product used. Its use was authorised by the Superintendent of Health.

Questioned by Dr Paris witness stated that Article 20 was used on the same basis as the use made in Clause 9 of a tender similar to the one in question. In the matter of the mentioned litigation witness confirmed that a Court injunction was met and that Cherubino are claiming *force majeure* regarding the inability to deliver. Witness confirmed that Cherubino is the only entity offering the rabies vaccine which was emanating from France.

This concluded the testimonies.

Dr Paris stated that there was a previous appeal on this tender which was identical to this one in all respects. Appellant has previously raised the point of *res judicata* as no appeal had been filed within the statutory period on the first decision. There are a number of Court of Appeal cases laying down the elements of a *res judicata* and all these elements are present in this case. Perhaps the Board might wish to reconsider this point.

On the matter of the merits of the case, said Dr Paris, the appeal has been diverted onto the question of registration – which it is not. In PCRB Case 1772 the PCRB decided that the declaration of the preferred bidder was not correct and therefore there was no alternative except disqualification. The argument in this case has nothing to do with geographical location of a country but on the fact that the preferred bidder is making a declaration in own name and own entity stating that it is authorised to trade in Europe. The market authorisation names only Moltek whilst the tender declaration is in the name of JVH which are not authorised to trade the product. Conversely Cherubino is authorised and is able to make such declaration. As confirmed by one of the witnesses no clarification was sought on this point. This is a Note 3 item and not rectifiable. This point is totally independent of the location of the country of origin of the product.

The declaration by JV, continued Dr Paris, renders its submission ineligible precisely on the same grounds that one of Cherubino's bids was rejected viz eligibility on Article 20. The preferred bidder made an incorrect declaration on the same basis and was accepted. The only avenue open to JVH to save its bid is to rely on Regulation 235 - that is relying on the capacity of other entities but if so it had to indicate through some form of documentation how that reliance would be available throughout the contract. Either the ESPD or a contract had to indicate this and as stated in the *Ministry for Gozo* Case the obligation when relying on third parties has to be substantiated through documents.

As regards the two types of registration, (210 days or Art 126A) Dr Paris said, there is no application therefore there is no 210 days registration and registration under Articloe 126A is rejected as the product is not emanating from the EU. Is the PCRB willing to allow the CPSU to award a tender knowing that it is going to lead to a contract that cannot be fulfilled? The use of Article 20 is an exception not the rule to be used exceptionally in an emergency. In the case referred to by the Authority only a small supply was authorised and only because supplies ran out. This is not the case in this tender. Using Article 20 as a form of registration is an abuse of power and bears no comparison to the rabies vaccine as in that case there is only one supplier with no alternative. The reality of this case is that there is a declaration by the preferred bidder which is not correct. The PCRB has had a chance several times to decide on this point – Cases 1772/1771/1823 all dealt with erroneous declarations. Article 62 of the PPR states that a bid has to be eligible from the start but has to conform.

Dr Desira said that Appellant had again referred to the *res judicata* claim which matter has already been decided but which does not apply to this Board and that is the close of this subject. As to the merits of the case the wording of the tender limits the answer solely to a 'yes' or a 'no' and does not allow any comments or room for clarification. Further when they refer to 'company' are

they referring to the bidder, supplier or manufacturer. There is no distinction between Europe and the European Union. The latter is a union not the geographic entity known as Europe. Proof has been given that the product Moltek is licenced by a European authority and JVH is authorised to trade in medicinal products in Malta. The PCRB needs seriously to emphasise to contracting authorities the need for clarity in the wording of tenders to avoid the current waste of time in appeals.

The Appellant, said Dr Desira, is clutching at straws in bringing up the point on proof of reliance. In reality only three entities are able to apply in a similar tender – the manufacturer, their agent and a parallel distributor. If one follows appellant's argument regarding a certificate of reliance then this points back to the manufacturer and would kill competition. The licencing of products costs lots of money and there is no point for the parallel distributor to register unless it is assured that it is successful – hence the need for the 90 days facility.

As regard the rabies vaccine tender, continued Dr Desira, due to the inability to register the product the awardee applied for Article 20 authorisation – if one is not allowed its use it would be superfluous to include it in the tender. If one fails to obtain a licence in 90 days assuming circumstances allow these can be extended to 120 days - but the PCRB cannot substitute a discretionary decision of the Superintendent of Public Health by deciding on this point themselves.

Dr Camilleri agreed that the *res judicata* matter was decided and in any case a fresh evaluation merited fresh revision and decision by the Board. On the point of Clause 3.8 of the technical offer form which was raised earlier; this is a fresh point and was not one of the grievances raised in the letter of appeal and should be ignored. The appeal is on what constitutes Europe and the issue of Turkey and the related product registration. On the issue of Turkey the tender document refers solely to Europe and one cannot narrow definitions but has to stick to the wording of the tender. The successful bid conforms with the tender specifications. Registration is not part of the procurement process but of the contract execution. The successful bidder is given the chance of committing itself to registering later and the bidder has every right to make use of this opportunity which once given must not be denied. A similar situation on the execution of a contract was dealt with in the case *Cherubino Ltd vs Director of Contracts* where it was held that the PCRB responsibility ceases once the contract is awarded. The lack of registration has consequences according to the terms of the contract. Under Clause 1.2.1 (ii) the tender allows the Contracting Authority to purchase on account – why deny this option if it is there? Clause 9.11 is also available to all bidders to make use of.

Dr Paris noted that Cherubino were excluded, according to a witness, because they claimed Article 20 option. The Board has the rights and powers, under regulations 90 to cancel the process. Reference to case *OK Ltd vs Director of Contracts*. The attention of the appeal was diverted to the question of registration, which in this case is immaterial, as the appeal was on the reply to Clause 3.8 and this was not challenged.

Dr Desira said the point raised on the Appeal case was legal rather than technical and cannot be raised at this stage of the hearing.

Dr Camilleri said that the Evaluation Committee had said that Cherubino's bid was refused as Article 20 should have been applied by the CPSU not by Cherubino.

The Chairman thanked the parties for their submissions and declared the hearing closed.

End of Minutes

The Board having considered the objection filed, noted the letter of reply and evaluated the Minutes as well as the submissions made by representatives of the parties resolves that:

1) As rightly pointed out in the course of the hearing the replies submitted in the tender document literature " *I confirm the company* ***I*** *{emphasis of preferred bidder] am representing is licensed by a competent authority in Europe to trade this product"* it is difficult to distinguish whether the statement is made on behalf of the agent, manufacturer or parallel distributor and a simple "Yes" or "No" answer makes it difficult to decipher.

2) It considers that an Evaluation Committee charged with the delicate task of re-evaluating a tender already adjudicated upon should not have been composed of a single person, as confirmed by a witness.

3) The drafting of the tender document, the bad formulation and architecture of the nomenclatures used leaves ample room for interpretation and impinges on equity, a level playing field, the promotion of competition and fair treatment.

Taking all these into consideration the Board concludes that:

1) The tender be cancelled in terms of Article 90(3) of the Public Procurement Regulations

2) The deposit be refunded to the Appellant.

Mr Lawrence Ancilleri	Mr Richard Matrenza	Dr Vincent Micallef
Chairman	Member	Member