PUBLIC CONTRACTS REVIEW BOARD

Case 1964 – CT2333/2023 – Supplies – Pneumococcal Polysaccharide Conjugate Vaccines – Lot 1

26th February 2024

The Board,

Having noted the call for remedies filed by Dr Andrew J. Zammit and Dr Jessica Camilleri on behalf of GVZH Advocates acting for and on behalf of Associated Drug Co. Ltd, (hereinafter referred to as the appellant) filed on the 22nd November 2023;

Having also noted the letter of reply filed by Dr Leon Camilleri and Dr Alexia Farrugia Zrinzo acting for and on behalf of Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 27th November 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 Vivian Corporation Limited (hereinafter referred to as the Interested Party) filed on the 27th November 2023;

Having heard and evaluated the testimony of the witness Mr David Caruana (Representative of Associated Drug Co. Ltd) as summoned by Dr Jackie Mallia acting for Associated Drug Co. Ltd;

Having heard and evaluated the testimony of the witness Dr Alison Anastasi (Representative of Central Procurement and Supplies Unit) as summoned by Dr Jackie Mallia acting for Associated Drug Co. Ltd;

Having heard and evaluated the testimony of the witness Professor Christopher Barbara (Representative of Mater Dei Hospital) as summoned by Dr Jackie Mallia acting for Associated Drug Co. Ltd;

Having heard and evaluated the testimony of the witness Dr Georgios Trimis (Medical Doctor - Paediatrician) as summoned by Dr Jackie Mallia acting for Associated Drug Co. Ltd;

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

Having noted and evaluated the minutes of the Board sitting of the 22nd February 2024 hereunder-reproduced.

Minutes

Case 1964 – CT 2333/2023– Supplies - Pneumococcal Polysaccharide Conjugate Vaccines

The tender was issued on the 25th October 2023 and the closing date was the 7th December 2023

The estimated value of this tender, excluding VAT, was € 957,180.

On the 22nd November 2023 Associated Drug Co Ltd filed an appeal against the Central Procurement and Supplies Unit objecting to the terms of the tender under Regulation 262

A deposit of € 4,785.90 was paid.

On the 22nd February 2024 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Dr Vincent Micallef as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Associated Drug Co Ltd

Dr Jackie Mallia	Legal Representative
Dr Jessica Camilleri	Legal Representative
Mr David Caruana	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Alison Anastasi	Representative

Interested Party – Vivian Corporation

Dr Clement Mifsud Bonnici	Legal Representative
Dr Calvin Calleja	Legal Representative
Ms Daniela Galea	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative

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

Dr Jackie Mallia Legal Representative for Associated Drug Co Ltd stated that the Contracting Authority claims that the Centers for Disease Control and Prevention (CDC) guidelines were being used in the parameters of this tender but the actual tender does not reflect this. The minimum 10-valent being requested does not cover all the risks prevalent in Malta. This will be confirmed by witnesses.

Dr Mark Anthony Debono Legal Representative for the Department of Contracts intervened to say that there has been a wrong interpretation of the tender as what is being asked is a range of valent and there is no basis for this appeal.

Mr David Caruana (834380M) called to testify by the Appellant stated on oath that he is a Pharmacist employed by Associated Drug Co Ltd. He said that the product offered by appellant was the most advanced in dealing with cases which fall under Lot 1 from babies of about three months to a year old. Clarification was sought (Clarification Note 3) to find out which guidelines the Authority was working to. These vaccines were meant to cover most types of pneumonia infections and therefore the higher the valent the more types of infections it covers. According to the Authority the CDC guidelines were being used which recommended a 15-valent be used in the case of children. The European Medicines Agency (EMA) only issues guidelines on best practice. The 10-valent product is cheap but it was being dropped from use in many countries as it does not cover a wide range of infections. The Appellant is asking that the specifications be altered in view of this.

In reply to questions from Dr Leon Camilleri the Legal Representative for CPSU witness said that he was a representative of Associated Drug Co Ltd and that in his testimony he was referring to guidelines that were in common use in most European countries.

Replying to questions from Dr Debono, witness confirmed that the tender did not indicate a specific value but stated 'at least 10-valent' but this does not cover all the risks that babies face and participation should not be on the basis of 10-valent.

Dr Alison Anastasi (393380M) called to testify by the Appellant stated on oath that she is the Head of Operations Procurement as CPSU and that she was not involved in the tender process. The tender was issued in two lots based on different valent. 10-valent is usually used for treatment under the listed schedule whilst Lot 2 is a new product approved for use on adults aged over 65 years. It is a condition that on this new medicine if the price is exceeded the lot will be withdrawn. On the recommendation of the Advisory Committee on Immunisation Practices (ACIP) the valent was increased to cover a wider range of risks. Witness agreed that the clarification referred to the CDC guidelines and that there is no equivalent body in Europe.

Questioned by Dr Camilleri witness repeated her occupation and confirmed that the tender specifications were provided by the Directorate for Pharmaceutical Affairs (DPA) before the issue of the tender and that the ACIP is the body that recommends changes in medication in this case. Countries are not bound to follow the CDC guidelines.

In reply to questions from Dr Debono, witness said that the National Immunisation Schedule was meant to reduce infections in children and is updated as necessary. The rule is that 10-valent is the minimum recommended.

Professor Christopher Barbara (615562M) called to testify by the Appellant stated on oath that he is the Clinical Chairman, Department of Pathology and is a member of the ACIP. Witness explained the object of the product in question and its use in fighting infections. A number of infections are more aggressive and therefore manufacturers produce medication to fight them and as a consequence they increased the range of protective valent. Witness went on to deal with the range of invasive and non-invasive infections, with the former creating most problems and requiring most attention. 10-valent covers only ten invasive types and the higher one goes the more types are covered. 10, 13 and 15-valent are all suitable for children but the higher one goes the higher the chance of hitting the infection.

Replying to questions from Dr Camilleri, witness said that 10-valent was used considerably in Malta. There are over 100 serotypes and companies try to create immunisation against most invasive types. The benefit of valent up to 15 is that it can be given at a very young age.

Dr Georgios Trimis (PP AY 2707906) called to testify by the Appellant stated on oath that he is a Paediatrician specialising in vaccines. He referred to the 10,13 and 15-valent vaccines and described what frames each covered. The most serious disease in Europe was pneumococcal disease. The 10-valent vaccine has low prevalence and countries using it have a lower rate of recovery, which however goes up as the valent increases. Only one country in Europe was still using 10-valent and most countries are now using 13 or 15-valent vaccines. The 10-valent is not registered in the USA where they use the 13-valent. In the case of infants 15-valent is recommended.

In reply to questions from Dr Camilleri, witness said that he works for MSD Company with responsibility for Malta Cyprus and Greece. The company produces 15-valent vaccines. Witness has no experience of working in Malta and he does not know the details of the tender in question.

Questioned by Dr Debono, witness stated that some serotypes prevalent in European countries are missing in the 10-valent vaccine and it's likely that the same types are prevalent in Malta. Nederland is one of the countries that have stopped using 10-valent.

This concluded the testimonies.

Dr Mallia said that the Appellant is only requesting that the tender is adequate to protect children. The prevalence of diseases most common must ensure maximum protection. If the CDC guidelines are followed 15-valent is the one which covers most dangerous infections. If the tender is followed as it is that means that for the next three or four years only 10-valent will be available and this does not give maximum protection.

Dr Clement Mifsud Bonnici Legal Representative for Vivian Corporation said that the Authority has the option to chose its medical requirements. The clarification was used by Appellant to ascertain certain facts and then use them to build the case for its appeal – a reverse process. Their argument is difficult to follow as the parameters of their appeal has changed as it went along. This appeal was not launched on the fact that 15-valent is more effective. The CPSU in its reply made the point that the CDC guidelines is not the tender document and it is this that determines the call.

Dr Debono stated that Appellant claims that there are illegalities in the tender but have not stated why the tender terms should be widened. No proof has been put forward that there are errors or ambiguities. What happens in America does not affect Malta. The 10-valent is sufficient for Malta's needs. Appeal should be denied.

Dr Camilleri said that the application is an attempt to restrict competition. The appeal was based on Regulation 262 (1)(b) on the clarification when in fact there was no contradiction in the reply to that clarification. The tender is open even to 15-valent but asking for a minimum of 10-valent. Appellant is asking that the tender is restricted to 15-valent. In Court of Appeal case 538/23 *Krypton vs CPSU* the Court held that the Contacting Authority is obliged to set terms that can be met, and that is the case here. The tender is clear and not ambiguous and the appeal should be rejected.

There being 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 sitting of the 22nd February 2024.

Having noted the call for remedies filed by Associated Drug Co. Ltd (hereinafter referred to as the Appellant) on 22nd November 2023, refers to the claims made by the same Appellant with regard to the tender of reference CT2333/2023 – Lot 1 listed as case No. 1964 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Jackie Mallia & Dr Jessica Camilleri

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

Appearing for the Interested Party: Dr Clement Mifsud Bonnici & Dr Calvin Calleja

Whereby, the Appellant contends that:

a) In the light of the conflict created between the Tender specifications set out under the heading "General Provisions" (paragraph 1.1) and the CDC guidelines which serve as the technical basis of the Tender, our client wishes to avail itself of the remedial procedure set out in Regulation 262(1) paragraphs (a) and/or (d) of the PPR, as the Board may consider appropriate, and this exclusively in relation to the specifications of Lot 1 of the Tender.
b) It is humbly submitted that any vaccines having a valency of less than 15 should not be invited to participate in the Tender for Lot 1 and the relevant Tender specifications for Lot 1 should read "a vaccine of at least 15-valent" to be consistent with CDC technical specification guidelines as clarified by the contracting authority in the clarification (CT2333_2023 Clarification Note no.3 Question 3).

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 27th November 2023 and its verbal submission during the hearing held on 22nd February 2024, in that:

a) At the time of the initial recommendation there were only two types of pneumococcal vaccination available for use in children, the 10-valent and 13-valent vaccines. Since there was no policy of universal pneumococcal vaccination in Malta as yet, ACIP considered that the use of the 10-valent vaccine would already provide benefit to the prevention of pneumococcal disease in the Maltese Islands. Furthermore, comparison was made with other European countries using this type of vaccine successfully. A recent comparative analysis of European and US National Immunisation Advisory Bodies' evolution of pneumococcal vaccine recommendations and criteria for decision making (Noharet-Koenig et al, May 2023) shows that the development of newer high valency pneumococcal vaccines has instigated some countries with a high burden of pneumococcal disease to recommend the use of these vaccines in lieu of lower valency ones. This is particularly the case for the United States where the 10-valent pneumococcal vaccine was never registered or licensed. On June 22, 2023, the American Advisory Committee on Immunization Practices (ACIP) convened and approved recommendations for the use of 20-valent pneumococcal conjugate vaccine in U.S. children. The ACIP recommendations were adopted by the CDC Director on June 27, 2023, and are now official.

b) This is definitely not the case in Europe where despite the EMA licensing of 15-valent pneumococcal vaccine for use in children in June 2023, European ACIPs and the European Centre for Disease Prevention and Control still hold that there is enough health benefit provided by the 10-valent and 13-valent vaccines in their National Immunisation Schedules for children. In fact, France and Belgium still use the 10-valent vaccine exclusively in their Schedule whereas Germany, Netherlands and Spain have both the 10-valent and the 13-valent vaccines in theirs.

c) The Maltese ACIP has reviewed its recommendations for universal pneumococcal vaccination in infants and concluded that it is still too early to recommend the exclusive use of the highest valency PCV vaccine currently licensed for children, thus excluding the 10-valent and the 13 valent. The Committee maintains that its recommendation to include at least a 10-valent pneumococcal vaccine in the National Immunisation Schedule three years ago is still relevant in the current local pneumococcal disease burden scenario, and this does not exclude the 15-valent vaccine.

d) CPSU submits that there is nothing contradictory in its replies to the clarification question. Although it does acknowledge that a 15-valent pneumococcal vaccine for children exists, on the basis of the ACIP's recommendations it decided to procure at least 10-valent for Lot 1, thus leaving competition open for the 10, 13 and 15 valent.

e) The contracting authority retains the discretion to purchase what it needs, without discriminating and this is what was done in this case. The approval of a new medicine, dose or indication does not mean that the contracting authority is bound to purchase exclusively products according to the latest international approval. This would run contrary to the basic principles of procurement and open competition when a less recent approval is still considered as effective. The 15-valent pneumococcal vaccine is thus eligible to compete for lot 1 which requests at least 10-valent. This requirement is therefore open, transparent and competitive and it is the applicant's action which is not and which is the contrary to what is usually expected from an application in terms of regulations 262 of the PPR!

f) Moreover and with reference to the remedy sought, CPSU strongly submits that there are no inconsistencies or clauses which are impossible to perform, and there are neither any errors. The CDC guidelines were consulted by the tender drafters but is not the tender document. As the applicant is well aware, ultimately it is the tender document and its conditions which determine the parameters of the call, and no other document. The tender document does not contain inconsistencies, clauses which are impossible to perform, and neither any errors. It is the contracting authority on the basis of the advice given shall determine its needs, and since these needs and conditions are well founded, legitimate and are made in order to maintain competition in line with regulation 39 of the PPR, the tender conditions should be confirmed by this Honourable Board as published.

This Board also noted the Interested Party's Reasoned Letter of Reply filed on 27th November 2023 and its verbal submission during the hearing held on 22nd February 2024, in that:

a) In many ways, the Appellant's application runs contrary to the objectives of the public procurement legislative framework inter alia Regulation 262 of the PPR. Rather than opening the technical specifications to allow for more competition, the Appellant is attempting to engineer a "contradiction" in the tender conditions to close competition and to make sure that its product is the only one admitted to this race.

b) First, there is no contradiction, as submitted by the Appellant, in the tender conditions. The Tender clearly requires, as a minimum, a 10-valent pneumococcal polysaccharide conjugate vaccine for Lot 1. In question 3 in Clarification Note 3, an economic operator, presumably the Appellant, asked the contracting authority to *"specify which guidelines have been taken into consideration for the specifications of Lot 1 and Lot 2"*. The Contracting Authority replied by (sic) that guidelines issued by CDC and EMA were duly considered. The term "consideration" connotes that the guidelines were "thought about" when the technical specifications were drafted by the Contracting Authority. The Contracting Authority may have taken on board some of those guidelines when drafting the technical specifications, but it was well within its discretion when it decided not to. The Contracting Authority did not say, in the Tender, that the vaccine to be offered under Lot 1 needs to comply or to conform with CDC guidelines. As such, the CDC guidelines are not part of the technical specifications for Lot 1 of the Tender. Therefore, there is no case of *"error [...] of a particular term or clause"* in the Tender in terms of Regulation 262(1)(d) of the PPR, as the Appellant alleges in its second requested relief.

c) Second, the Tender, as drafted, is compliant with the PPR and the general principles of public procurement law: promotion of genuine competition, equal treatment and transparency. The technical specifications for Lot 1, in particular, the minimum specification for *"at least 10-valent"* is fair, open and non-discriminatory. The Appellant's product, which is a 15 valent vaccine, is not excluded by the technical specifications for Lot 1. Therefore, there is no case of *"clauses [...] which are proven to be impossible to perform"* in terms of Regulation 262(1)(a) of the PPR, as the Appellant alleges in its first requested relief. Rather, the Appellant is seeking to change the technical specifications for Lot 1 such that it excludes other vaccines from Lot 1, and thereby, artificially narrowing competition and unduly favouring its product.

d) Third, as shall be shown during the proceedings, this Honourable Board, and the Court of Appeal, has already rejected similar applications in the past, in part, for the reasons aforesaid.

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 witness duly summoned, will now consider Appellant's grievances.

a) In both written and verbal submissions, the appellant claims that the CDC guidelines were being used in the parameters of this tendering procedure. Whilst it is correct to state that such guidelines have been given due 'consideration', by the Contracting Authority, (reference to clarification number 3), it is also correct to state that any reference to such guidelines does not feature at all in the tender document. Therefore, it is this Board's opinion that once these have not been specifically referred to in the tender dossier, these are not to be deemed as a mandatory requirement imposed on the Contracting Authority.

b) It has been ascertained through the testimony under oath of Dr Alison Anastasi, that the tender specifications were provided to the Contracting Authority by the Directorate for Pharmaceutical Affairs (DPA) and that it is the ACIP which recommends changes in the medication subject matter of this appeal. Currently, the rule set by ACIP, is that the 10-valent is the minimum recommended. Therefore, this Board opines that the Contracting Authority has adhered to best practice procedures and the technical specifications, as drafted, are also in line with what the body responsible for such medication in Malta recommends.

c) Reference is now made to Regulation 262(1)(a) of the Public Procurement Regulations whereby it is stated *"..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;..*** *"* (bold emphasis added). This Board opines that no proof has been presented that the technical specifications as drafted are 'unlawful' or else 'impossible to perform'.

d) Reference is made to Regulation 262(1)(d) of the Public Procurement Regulations whereby it is stated *"..to correct* ***errors*** *or to* ***remove ambiguities*** *of a particular term or clause included in a call for competition, in the contract documents, in* ***clarifications*** *notes or in any other document relating to the contract award procedure;"* (bold emphasis added). This Board opines that no proof has been presented that the tender as drafted and / or the clarification as presented included errors and / or ambiguities.

e) From a purely public procurement point of view, as is the remit of this Board, the remedy being sought by the appellant runs somewhat contrary to the true spirit of a 'Remedies before closing date of call for competition'.

Hence, this Board cannot but reject the Appellant's grievances.

The Board,

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

a) Does not uphold the Appellant's concerns and grievances;
b) That the deposit is not to be refunded to the Appellant.
c) To order the Contracting Authority to amend the closing date of the call for tenders at its discretion whilst keeping in line with the public procurement regulations.

Mr Kenneth Swain	**Dr Charles Cassar**	**Dr Vincent Micallef**
Chairman	**Member**	**Member**