PUBLIC CONTRACTS REVIEW BOARD

Case 1328 – CT 2112/2019 – Tender for the Supply of Pneumococcal Conjugate Vaccine

Remedy before Closing Date of a Call for Competition

The publication date of the call for tenders was the 3rd June 2019 whilst the closing date was the 20th June 2019. The estimated value of the tender (exclusive of VAT) was € 3,401,440.

On the 19th June 2019 Vivian Corporation Ltd sought a Remedy against the Central Procurement and Supplies Unit as the Contracting Authority requesting cancellation of the tender on the basis that it is in violation of any law.

On 11th July 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Richard Matrenza as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Vivian Corporation Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Dr Chris Grech	Legal Representative
Ms Joanna Gatt	Representative
Mr Kenneth Briffa	Representative
Dr Vasiliki Kossyvaki	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Stefan Zrinzo Azzopardi	Legal Representative
Ms Denise Dingli	Representative
Dr Alison Anastasi	Representative
Ms Tracy West	Representative

Department of Contracts

Dr Franco Agius	Legal Representative

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr Clement Mifsud Bonnici Legal Representative for Vivian Corporation Ltd started by saying that there are three grounds on which his clients are objecting. There was a scientific objection about the product and two legal points covering duration of tender and urgency of the closing date. His clients were requesting the cancellation of the tender entirely. He went on to outline the type and purpose of the Pneumococcal Conjugate Vaccine (hereinafter referred to as the vaccine) and of its use mainly in the protection of pneumonia and meningitis. The tender treats two different products – a 10-valent and 13-valent serotypes as one vaccine.

Dr Alison Anastasi (398384M) called as a witness by the Public Contracts Review Board (PCRB) testified on oath that she is a Pharmacist and has been a member of the Immunisation Advisory Policy Committee (IAPC) for a number of years. She is aware that the vaccine was first recommended for use in 2009. Witness confirmed that that there is no age usage indicated in the tender. The IAPC made a recommendation on the use of the vaccine and the Directorate for Pharmaceutical Affairs (DPA) approved the tender specifications. The specification missed an important factor namely the age usage – it is meant for children up to five years of age - this was not stated in the tender document.

Dr Vasiliki Kossyvaki called as witness by the Appellants testified on oath that she is a Greek national and a Doctor of Medicine with a Masters Degree in Health Economics, and has specialised in lung diseases. She has been working in the Pfizer vaccines department since 2014.Witness went on to explain that serotypes vaccines act against a bacterium that affects young children who can transmit it to other children and it can cause death. Treatment can range from minor infections like otitis to major ones like pneumonia which is a main cause of mortality worldwide, with young children mainly at risk. The vaccine is designed to prevent the process of infection through recognition of the Streptococcus. There were two products on the market Synflorix and Prevenar. The earlier ones did not work very well on children. Prevenar was first licensed around the year 2000 and was a preventative against seven serotypes. At this stage witness tabled documents marked VCL 1 to 20.

There was a short recess to enable parties to acquaint themselves with the extensive documentation tabled.

Resuming her testimony witness stated that Prevenar proved to be very successful in the treatment of infants. In 2009 Synflorix which protects against 10 serotypes was introduced and Prevenar 13 (13 serotypes) was first used in 2010. There is a substantial difference between the two products in that Synflorix is licensed to be used up to the age of five years whilst Prevenar can be used from six months to any age over 5 years, as well as on patients with special conditions. Reference was made to Doc VCL 10 which indicates a difference between the dosages administered in the schedule of the two products. Many countries use Prevenar which has added value due to the additional serotypes.

Witness referred to the vaccination process in Belgium where Prevenar 7 was in use between 2007 and 2011. In the latter year Prevenar 13 was introduced and this led to a decline in the various diseases especially from the 19A bacterium. In 2015 to control costs the Belgian authorities started using Synflorix and for the next three years the incidence of disease started rising. In 2018 the areas of Flanders and Wallonia went back to using Prevenar 13.

Questioned by Dr Agius Legal Representative of the Department of Contracts, witness stated that Synflorix does not cover bacterium 19A which is the fourth most prevalent disease all over Europe. Witness confirmed that she was not aware if any 19A bacterium infections had been identified in Malta.

Dr Victoria Farrugia Sant' Angelo (138358M) called as a witness by the PCRB testified on oath that she is a Medical Doctor and for three years has been the Chairperson of the IAPC, having been a core member since 2007. The committee was responsible for the national immunisation programme of vaccines covering children from two months to sixteen years. Since 2009 the committee has been recommending that both vaccine formulations would result in a reduction of pneumo invasive diseases. There were very limited epidemiological studies locally so the committee based their recommendations on international studies. Witness was not aware of what vaccines other countries are using – her committee looked at the World Health Organisation (WHO) paper (tabled as Doc 21) which shows no difference in the results obtained from the type of vaccine formulation used (see page 93 third paragraph). Witness agreed that Prevenar 13 has three extra serotypes and according to her, children need just one dose of either vaccine for ages from two to five years. This last statement was further confirmed in reply to a question posed by the Chairman.

Dr Agius asked that it be recorded that he was formally objecting to a question put by Dr Mifsud Bonnici regarding the personal preference of vaccine used by the witness. Later on in the hearing Dr Mifsud Bonnici asked that it be formally recorded that he was not being allowed to ask witness her personal choice of vaccine which according to him had a bearing on the case, and he objected formally to the Board that his pertinent question was being opposed by the Department of Contracts.

Proceeding with her testimony witness stated that the WHO does not impose the number of vaccine doses administered but gives two options. Shown Summary of Product Characteristics (SPC) of both products, witness agreed that in the case of patients between two months and seventeen years Prevenar recommended one dose whilst in the case of Synflorix it was recommended that two doses are administered in children between twelve months and five years.
Dosage was never discussed by the IAPC as their aim was to vaccinate all children at birth and they had not considered older ages. The committee recommended a policy for the introduction of a vaccine on new born children from the age of two months and it was not their remit to cover

what ages were immunised. She could not conclude that out of the two products one was more effective medically or cost wise than the other. Extract from the Department of Health's Internal Immunisation Report was tabled (Doc 22).

Witness confirmed that she was not aware of the details of the Belgian case and what prompted the authorities to change the vaccines. The Government of Malta does not have the funds to carry out studies on the effectiveness of vaccines and does not see the utility of it as the policy is to vaccinate generally. She was in agreement that it would be correct to state that one of the vaccines is superior in providing protection, but it is not the aim of the Government to introduce a vaccine other than for children. As far as witness is aware there are two documented cases of elderly persons suffering through lack of vaccination – for different purposes the two vaccines are not equivalent, but both are equivalent in reducing the incidence of pneumo infections in children. It is a matter of fact that Prevenar contains 19A serotype, however all studies indicate that both vaccines have the same effect in children up to five years.

In reply to a question by Dr Stefan Zrinzo Azzopardi Legal Representative of the Central Procurement and Supplies Unit, witness stated that the objective of their policy is to introduce a product that will reduce the incidence of diseases - in that respect both products were effective and licensed in reaching that aim, although Synflorix does not provide protection against the 19A bacterium.

Dr Christopher Barbara (615562M) called as a witness by the PCRB testified on oath that he is a medical microbiologist and Clinical Chairperson of the Pathology Department at Mater Dei Hospital. He has been an advisory member of the IAPC for around ten years. In 2017 he had prepared a paper for the Superintendent of Public Health giving a diagnosis of infectious diseases to enable doctors to choose the right antibiotics. There was an epidemiology study by Dr Paul Cassar going back to 2009/2011 but the numbers recorded were very small – there were three cases of Type 3 bacterium, one case of 19A, one case of 6A. In eleven years there were two deaths from the 19A bacterium. (At this stage the Chairman released the witness from his professional oath of confidentiality to enable him to proceed with his testimony).

According to Dr Zrinzo Azzopardi one of the latter cases was a 10 month old baby.

Answering questions witness stated that countries changed from a 13 to a 10 serotype vaccine only following a cost benefit analysis. The effectiveness of 10 over 13 serotype vaccine is in money terms. He was not aware that the majority of European countries use Prevenar, or that the Health Authorities in the UK recommend it nor of the Belgian case. However he was aware that two regions in the UK use Synflorix. The whole aim of the exercise was to decrease the burden of invasive diseases.

Mr Kenneth Briffa (418675M) called as a witness by the Appellants stated on oath that he was a pharmacist and has been employed by Appellants in charge of the vaccines portfolio since 1998. When he was referred to paragraph 26 of the reply letter from the Department of Contracts, he stated that in his experience the statement was incorrect since parents prefer Prevenar which gives better protection.

Dr Mifsud Bonnici said that he would deal first with the second and third objections as these were matters of a legal nature. Dealing first with the duration of the tender he said that it was up to the PCRB to give direction as to whether a tender duration of 36 months extendable by a further year would close competition and remove the Government's ability to procure modern and newer medications. The tender breaches two principles of public procurement regulations. He referred to Case 1279 Charles De Giorgio Limited vs CPSU heard by this Board which decided that there is no risk for patients in switching between different vaccinations if the period is short. More importantly the principle of proportionality was being breached. The Contracting Authority must not exceed the limits of what is necessary and appropriate. The time period for vaccinations for children at two months and four months is very short and in practice this can be rolled out in one year assuming the tender is done properly and there are no challenges or remedies before contracts are sought. This is an open tender and not a framework agreement and there is no need for such a long duration.

With regard to the urgency aspect Vivian Corporation agree that the matter is urgent in that the vaccination policy should have been introduced years ago. Delays on the part of the Government should not affect economic operators. The tender should be cancelled and re-issued (if at all) allowing a longer period for submission of the offer. The tender is not drafted correctly with no indication that it is an accelerated tender and with serious divergence in dates indicated in the documents. It was only after clarification that this error was amended. The PCRB must advice Contracting Authorities that this does not happen again and urgency does not mean that public procurement regulations are ignored. The recommendation that the vaccine should be introduced goes back to 2009 and a financial commitment to introduce it was mentioned in the 2017 budget- so where is the urgency? The Board should give a clear signal that this accelerated procedure mentality is not acceptable by cancelling this tender. Following an OECD report there was a recommendation by the National Audit Office that it is unfair on other economic operators to have an accelerated procedure because it might put them off tendering due to the pressure of time to submit an offer. The rationale of the European directive is that the period of time must be correct on the first issue of the tender. Reference was made to European Court of Justice Case C518/17 (tabled as Doc 23 para 71) wherein it was decided that in instances of prior missing information it was up to national law to decide whether to declare a document null because of that defect. The period of tender submission was in breach of Article 49 of the European directive because it was too short.

With regard to the technical specifications, Dr Mifsud Bonnici stated that the idea that two products will reduce the burden of disease does not equate with the concept of functional principles of public procurement or lend any credibility to the argument that the two products are equivalent – the composition of the products is different. The question of serotype 19A is not to be taken lightly; this is not an imaginary argument because this disease exists in Malta, and it was ill-advised of the Contracting Authority to put the two products in the same basket. The Belgian case and the reasons why they switched to Prevenar 13 are amply documented in Doc VCL 12. As it is the tender is illegal as it cannot treat different products as if they were the same. Furthermore the tender does not state the age group, and there is a lack of equality in the number of doses suggested. Since the technical specification are illegal and for the reasons mentioned there will be a lack of equality in the evaluation of bids.

Dr Agius said that all that the tender documents set out to do was to establish a minimum baseline of ten serotypes – based on that the cheaper product will win the tender. A fundamental element of public procurement is getting value for money. The aim is to achieve a basic coverage for all children in Malta. The Contracting Authority's decision is based on unbiased studies whereas those by Appellants are mostly sponsored documents. Doc VCL 16 page 7 says that there is equivalence in serotypes. Witness Dr Farrugia Sant'Angelo stated that there is equivalence in the vaccines to the benefit of the Government. Clause 46 of the preamble of the European directive (tabled as Doc 24) allows shortening of open procedures if impracticable because of a state of urgency – it does not need to be extreme urgency. In the open procedure directive it states that the term urgency has a lower meaning and may be brought about by the Contracting Authority itself. Urgency is objective and in this case it is justified and there is no reason to cancel the tender. Reference was made to Court of Appeal Case 177/2007 (Tabled as Doc 25) where the Court decided that the actions of the Director of Contracts superseded the breach of regulations. In any instance the 30 day period was exceeded by the many extensions given in the tender documents.

Contrary to the submissions made, the contract period is three years not four. Any extension needs to be approved by the Director of Contracts and the General Contracts Committee. It must not be taken for granted that a fourth year is given. Belgian law establishes that justification is required to issue a four year tender. Maltese law imposes limitation on framework agreements but imposes no limitation on open procedures as a standalone contract. . The Contracting Authority needs a three year contract to ensure security of supplies – this aspect is supported by ECJ decisions. There is no reason to cancel the tender. The market is open to anyone whose products exceed the ten serotypes and the duration of the tender is not anti-competitive.

Dr Zrinzo Azzopardi pointed out that the urgency in the tender was due to the seasonality when the vaccine was administered – i.e. before the approach of winter.

Dr Mifsud Bonnici in his closing remarks said that when it comes to the duration of a tender the Contracting Authority is constrained by general procurement principles and they need to act in a

proportionate manner. If the Authority wanted to save time they could have found time in reducing the evaluation process not on shifting the burden on the economic operator. The technical specifications do not stipulate minimum bench marks as claimed by the Contracts Department – it merely states 10-/13- valent with no minimum baseline. Pages 7 and 8 of Doc VCL16 shows the increase in incidence of the 19A bacterium. The objection of Appellants is that Prevenar and Synflorix have been treated the same – only Prevenar 13 gives protection against 19A. Dr Barbara confirmed that in Malta only Prevenar gives protection against the 3 additional bacteriums.

Dr Agius accepted that the tender does not set a minimum requirement of serotypes, but there exists the possibility that the child who died from 19A Bacterium could have been vaccinated in England.

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

This Board,

having noted this 'Call for Remedy Prior to the Closing Date of a Call for Competition' filed by Vivian Corporation Limited (herein after referred to as the Appellants) on 19 June 2019, refers to the claims made by the same Appellants with regard to the tender of reference Ct 2112/2019 listed as case no 1328 in the records of the Public Contracts Review Board.

Appearing for the Appellants: **Dr Clement Mifsud Bonnici**
Dr Chris Grech
Appearing for the Contracting Authority: **Dr Stefan Zrinzo Azzopardi**
Appearing for the Department of Contracts: Dr Franco Agius

Whereby, the Appellants contend that:

a) **There are two different products which can satisfy the technical specification, and these are 'Synflorix' and 'Prevenar' however, these two products are functionally and therapeutically different and provide different age coverage;**

b) **the contract period is too long so that it is restricting participation with more updated products which might be available on the market during the thirty-six months with an option for a further extension of twelve months;**

c) **no mention is being made in the tender dossier as to why this procurement is being required on such an urgent basis, as duly stipulated in regulation 122 of the Public Procurement Regulations.**

This Board also noted the contracting Authority's 'Letter of Reply' dated 4 July 2019 and its verbal submissions during the hearing held on the 11 July 2019, in that:

a) **the clinical particulars of both products are compliant with the technical requirements of the tender, taking into consideration that such product**

is intended to be applied on infants, so that, the age factor variation is irrelevant,

b) the Authority also insists that the period of the contract is within the parameters of the Public Procurement Regulations and the main objective of the Authority is to ensure that the vaccination programme can rely on a run of three years without any clinical problems,

c) the Authority would also state that this is an open procedure tender and regulations 122 and 121, being quoted by Appellants, refer to a restricted procedure, so that the mentioned regulations do not apply in this particular case.

This same Board also note the testimony of the witnesses namely:

Dr Alison Anastasi – duly summoned by the Public Contracts Review Board

Dr Vasiliki Kossyvaki – duly summoned by Vivian Corporation Limited

Dr Victoria Farrugia Sant'Angelo – duly summoned by the Public Contracts Review Board

Dr Christopher Barbara – duly summoned by the Public Contracts Review Board

Mr Kenneth Briffa – duly summoned by Vivian Corporation Limited.

This Board has also taken note of the documents submitted by:

Dr Kossyvaki - marked as VCL 1 to 20

Dr Victoria Sant'Angelo – marked as Doc 21 and Doc 22

Vivian Corporation Limited – marked as Doc 23

This Board, after having examined the relevant documentation to this 'Call for Remedy' and heard submissions made by the parties concerned, including the testimony of the technical witnesses duly summoned, opines that the issues that merit consideration are:

- **The difference in products**
- **The contract period**
- **Urgency of tender**

1. **Before entering into the merits of this application for remedy, this Board would point out that, in its deliberation, weighted reliance on the testimony of the witnesses was considered by this Board, due to the technical and medical nature of the product.**

2. **From the documentation and submissions made during the hearing, this Board was made aware that, there are only two products on the market**

which are compliant with the requirements of the Authority namely, 'Synflorix' and 'Prevenar'. They contain the same therapeutic values however, 'Prevenar' has the clinical ingredients to cover prevention of invasive disease for ages six weeks to seventeen years of age, whilst 'Synflorix' provides the same prevention coverage ages from six weeks to five years of age.

3. **Appellants' contention in this regard is that, these two products should not be treated the same as 'Prevenar' vaccine contains more protection against the bacterium 'Streptococcus Pneumoniae' than 'Synflorix', as can be seen from the following table:**

"While Synflorix is a 10-valent vaccine; Prevenar 13 is a 13-valent vaccine. The difference between a 10-valent and a 13-valent vaccine for Streptococcus pneumoniae is that the former protects against 10 different serotypes of bacterium while Prevenar 13 protects against 13 different serotypes of the same bacterium, as follows:

S. pneumoniae bacterium type	Synflorix	Prevenar 13
1	X	X
3		X
4	X	X
5	X	X
6A		X
6B	X	X
7F	X	X
9V	X	X
14	X	X
18C	X	X
19A		X
19F	X	X
23F	X	X

As can be deduced from the above table 'Prevenar' is the only one which contains 3, 6A and 19A which protects against these three serotypes, so that, in this respect, the two products can be considered similar but not the same.

4. **One has to determine the main objective of the Authority and from the testimony of Dr Alison Anastasi, it was confirmed that the immunisation programme is for children up to the age of five years. At the same instance, through the testimony of Dr Farrugia Sant'Angelo, this Board was made aware that the dosage for children of two to five years both 'Synflorix' and 'Prevenar' are the same so that, both mentioned products up to the age of five years are considered similar and in this regard, an extract from the testimony of Dr Farrugia Sant'Angelo confirms such an eventuality, as follows:**

"Chairman: *Dr Farrugia St Angelo, qed jissemma Prevenar 13 u Synflorix. Id-doses huma l-istess fl-opinioni tieghek?*

Witness: *l-ischedule hija l-istess iva. Jigifieri skont l-eta. Kemm tuza.*

Chairman: *From 2 to 5 years qed nghid*

Witness: *l-ghan tar-recommendations taghna*

Chairman: *Inbidlet*

Witness: *Le ma nistax nghid li mbidlet ghax ahna r-recommendation taghna hija ghal tfal minn 2 months*

Chairman: *Mela ejja niehdu 2 to 5. Id-dosage tal-Prevenar 13 u ta' Synflorix*

Witness: *Huma l-istess*

Lawyer: *Iva dan hu l-position paper. Dan qrajtu jien. Imma jien minix l-esperta*

Lawyer: *Ahna tlabna li jkollna kopja ta' dan ir-rapport peress li inti ghamilt refenza ghalih. Mhix kwistjonu ta' expertise pero r-rapport illi bdejt taghmel referenza meta ghitilna r-recommendations WHO huwa dak ir-rapport?*

Witness: *Iva this is the report"*

It is evident that the Authority failed to indicate, in the tender document that, such a vaccine is intended for children up to five years and up to this stage of vaccination age, both products can participate in this call for competition, so that this Board does not find any justifiable cause to deem that one of the products has an overall advantage over the other, for the vaccination programme, up to the age of five years.

5. With regard to Appellants' contention that the technical specifications are illegal, this Board opines that the only defect that exists in such

specifications is the fact that, same specifications omitted an important detail with regard to the application of age to the vaccination programme.

6. With regard to Appellants' second contention in that, the period of the tender is too long and is restricting the introduction of innovative products that may be available during the contract period, this Board acknowledges the fact that, from a clinical point of view, sufficient time is required to establish security of supply. At the same instance, the three-year period is well within the reasonable period for such a contract that will allow the Authority to carry out its vaccination programme without any unforeseeable glitches.

7. With regard to the possibility of an extension to the contract by a further year, this Board is well aware that, innovative medical products are always being introduced on the markets and for the benefit of the patient, the Authority should always seek to obtain the best product available. In this respect, this Board opines that, in this circumstance, an extension to the three-year period by a further year, would, in actual fact, delay the introduction of any new available and more updated products to be procured. It is the responsibility and obligation of the Authority to

ensure continuous supply after the third year of the tender by ensuring that the immunisation programme will continue, after the third year and by issuing, in advance, another call for procurement.

8. **With regard to Appellants' third contention, this Board would respectfully point out that this tender is an open procedure so that regulation 11b (3) applies. In this respect, there must be an urgency and there must be justification duly approved by the Director of Contracts, through which a date is fixed for the closing date of submissions to be not less than fifteen days from date of notification.**

9. **This Board acknowledges that the urgency of this case is primarily the continuance of the immunisation programme for children, thus justifying an eminent cause and such a fixed date was approved by the Director of Contracts. At the same instance, this Board notes that the Authority published its justification in the contract notice, the latter of which forms part of the tender document. In this regard, this Board does not find any justifiable cause which such urgency would affect or disrupt the participation of the Appellants in this open call for competition.**

In conclusion, this Board opines that,

a) **for the immunisation programme of children up to five years of age, both 'Synflorix' and 'Prevenar' are both compliant with the technical requirements as stipulated in the tender document,**

b) **the tender period should not exceed three years, so that open opportunities are provided for the procurement of innovative products available, after the three-year period. At the same instance, no extension of additional period should be stipulated in the tender document,**

c) **there exists sufficient justification for the deadline established for submissions of offers whilst, at the same instance, this Board confirms that the tendering procedure is an accordance with the Public Procurement Regulations.**

In view of the above, this Board,

i) **directs the Authority to include, by way of a 'clarification note', in a clear and precise mode, the main objective of the immunisation programme and to reflect for which age group such a programme is intended,**

ii) directs the Authority to exclude, by way of a 'clarification note', the possible extension of one year,

iii) upholds the contention that both 'Synflorix' and 'Prevenar', although different, will serve a similar function, in the tendered immunisation programme.

iv) the closing date for submissions is to be fifteen day from the date of this decision.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Richard A Matrenza Member

8 August 2019