PUBLIC CONTRACTS REVIEW BOARD

Case 1324 – CT 2056/2019 – Tender for the Supply of Diphtheria, Tetanus, Polio, Pertussis, HIB and Hepatitis B Vaccine

Remedy before Closing Date of a Call for Competition

The publication date of the call for tenders was the 20th March 2019 whilst the closing date was the 25th April 2019 (extended to the 28th May 2019). The estimated value of the tender (exclusive of VAT) was € 1,762,200 for 36 months.

On the 6th May 2019 Cherubino Ltd sought a Remedy against the Central Procurement and Supplies Unit as the Contracting Authority complaining that the tender as issued is limiting fair competition.

On 28th June 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Vincent Galea	Legal Representative
Dr Francis Basile Cherubino	Legal Representative
Mr David Basile Cherubino	Representative
Dr Salvatore Parisi	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Denise Dingli	Chairperson Evaluation Committee
Mr Julian Pirotta	Representative
Ms Tracy West	Member Evaluation Committee
Mr Karl Farrugia	Representative
Dr Tanya Formosa	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 Vincent Galea Legal Representative for Cherubino Ltd requested that before proceeding a witness be asked to state the source of the specifications in the tender document.

Dr Tanya Formosa stated that she formed part of the directorate responsible for drafting the tender. The Process Committee recommended the specifications which were endorsed by the Advisory Committee on Immunisation Policy which approved the vaccine. Witness was not aware of who drafted the tender specifications.

Dr Victoria Farrugia Sant Angelo (138358M) called as a witness by the Public Contracts Review Board testified on oath that she was the Chairperson of the Advisory Committee on Immunisation. The tender was drafted in line with the specification laid down in the 2010 standards of the World Health Organisation (WHO) with, on this occasion, the additional antigen. No changes were made to the 2010 standards.

Dr Salvatore Parisi called as a witness by Appellants testified on oath that he was an Italian medical doctor who specialises in Preventive Medicine, and had done work in this sphere for the WHO and currently works for Sanofi Pasteur (Sanofi), a company that specialises in vaccines for a variety of diseases. Referring to Section 4 paragraph 1.1 of the tender specifications witness stated these ingredients and quantities are derived from standards set by the WHO for protection from diseases. After this stage they are normally clinically tested followed by tests on patients. Registration by the WHO and the European Medicines Agency (EMEA) confirms that they meet the necessary standards.

Dr Francis Cherubino Legal Representative of Cherubino Ltd stated as background information that the tender deals with vaccines for infants and follow-ups later at different stages of their life. There is a schedule of vaccinations at various ages. The vaccine presently consists of five components plus one for Hepatitis B. The Department of Health is now trying to combine six components in one (Hexavalent). The Central Procurement and Supplies Unit (CPSU) instead of following the WHO recommendations in their entirety has instead picked bits and pieces of this recommendation thereby restricting the tender to only one supplier – GSK, thus infringing competition laws. Appellants are following the recommendation of the WHO as reviewed by EMEA in the product they have to offer. If the WHO recommendations are followed then the tender cannot be restricted. Appellants can offer exactly the same product in regard to the contested products covering diphtheria and pertussis as they all meet international requirements. The tender restricts measurements to International Units (IU) and is not open to milligrams measurements as the Appellants' product.

Dr Franco Agius Legal Representative of the Department of Contracts said that in Malta the five in one vaccine (5in1) was currently in use. The Health Authorities have now decided to change to a six in one vaccine (6in1) in lieu. The measurements of the vaccines newly procured have to be compatible with previous measurements as these have an effect on the efficaciousness of the medicine on the patient.

Dr Cherubino said that with the current product one cannot move from a penta (5 in 1) to a hexa (6 in 1). His company was offering a product in line with WHO specifications and that met international standards.

Dr Parisi resuming his testimony tabled a paper covering Hexavalent Vaccine Market Study (Doc 1) which shows that Hexaxim (Sanofi product) has a market share of vaccines by volume of 63% worldwide. Doctors in private practice prefer one simple vaccine to administer and it is also safer and avoids misuse through human factors. The Sanofi product is approved by the WHO and EMEA and unlike the GSK's product does not need a preparation process to administer. The WHO allows different methods for the measurement of antigens and offers options other than those stipulated in the tender – for example with the diphtheria vaccine it allows lower limits of measurements.

Witness tabled a document produced by Sanofi (Doc 2) showing the measurement requirements for diphtheria and pertussis and indicates that alternative concentrations are allowed by the WHO as exemplified in Hexaxim which contains less than 20 IU per dose. The effect between 20 IU and 50 IU is not different according to WHO.

Witness went on to table a document on Hexavalent vaccines (Doc 3) showing the vaccine characteristics and the quantity of antigens which varies in the three different products but which all meet the WHO criteria. This was a sponsored study and not a WHO document but it still indicated that all criteria are met. In a further document tabled on Product Characteristics (Doc 4) it is clearly stated that one can switch from a penta to a hexa vaccine in the case of a booster thus shortening the time between vaccinations.

Mr Karl Farrugia Representative of the CPSU stated that the Government of Malta decided to change from 5in1 to 6in1 as the Hepatitis B vaccine was become scarce and not freely available. In changing to 6in1 the Medical Authorities were taking the least possible risk by following medical advice and sticking to the parameters set in the tender specifications. If any changes were envisaged there must be no risk to patients.

Dr Cherubino said that there has to be change as tender as currently drafted is limited in competition and not following public procurement practice.

Dr Farrugia Sant Angelo recalled to give further testimony confirmed that section 1.1 of Clause 4 of the tender documents had been reproduced from the WHO specifications. Flocculation units (LF) were an alternative measurement for units previously used by the WHO. Referring to Doc 2 previously tabled, witness stated that 30 IU is the median measurement but it can be varied to a higher or lower figure – for example 15 IU is the dose usually given to adults. When dealing with the immunisation of children the WHO gives arrange of 15 to 60 IUs in combination vaccines.

Dr Agius tabled a WHO Information Sheet (Doc 5) on diphtheria vaccines but according to witness this was not relevant as it referred to a single vaccine not a combination.

Continuing her testimony witness stated that there were two reasons why Government was moving from a 5in1 to a 6in1 – firstly to minimise the discomfort to patients and secondly because of the worldwide shortage of Hepatitis B vaccine. Studies have shown that the same family product (i.e. vaccines produced by the same manufacturer) should be used to keep immune levels at peak. Switching between different products was not highly effective although no studies were yet available about the mixing of products. A document on Hexavalent vaccines (Doc 6) was tabled. This was a study sponsored by GSK which stated that switching between their products was possible without increasing dosage but that there are currently insufficient data available to support interchangeability from different manufacturers.

Witness re-iterated that the specification in the tender were those laid out in 2010 plus the added necessary Hepatitis B vaccine. The Department of Health was only concerned with continuity of supplies not compatibility of products.

Dr Cherubino said that there is no evidence in the summary of product characteristics to say that these products can be switched or that they were licensed by the EMEA. Doc 5 refers only to single component vaccine and he had reservations thereon. He tabled a WHO publication (Recommendation for Combined Vaccines) (Doc 7) and referred to the part where the WHO accepts 95% confidence in level of estimated potency - i.e. within the 50-200% range. The point of challenging the tender was that its terms are in line with GSK products and if necessary the tender should be cancelled

Resuming her testimony Dr Farrugia Sant Angelo said that there was no objection to widening the terms of the tender as long as those terms were within the WHO guidelines. The primary course is 3 doses at 2,3 and 4 months and then a booster when a different product can be used. In the case of diphtheria the WHO lays down that for children the dosage must be 30 IUs but in combined vaccines it can be lower ranging from 15 to 60 IUs. The lower the units the less is the chance of having full immunity. A 95% confidence level is acceptable by the WHO as reaching full immunity.

Dr Cherubino stated that the technical specifications as issued limit competition. There is no basis or scientific justification for the specification as drafted. Appellants' vaccine was in use in 80% of the world and accepted by the WHO. EMEA says that at 18 months it can be interchanged but Appellants' suppliers believe that interchange can take place at any stage. GSK's position is challenged as no similar study has been attempted by them. The Contracting Authority should have acknowledged and quantified the existing children and new born babies. They should have options available otherwise the process is prejudiced. The tender should be cancelled and redesigned to give a level playing field.

Dr Agius said that the tender established specific requests. Witness Dr Farrugia Sant Angelo stated that the requirements had been in place since 2010 and since then there has been healthy competition until the introduction of the Hepatitis B vaccine. Due to the shortage of the latter children are suffering, and this tender will put this right. The specifications are in line with the WHO guidelines and the Department of Contracts insists that clarification to change terms of tender is not possible and if the PCRB is minded to change the terms then the tender has to be cancelled and re-issued.

Dr Marco Woods Legal Representative of the CPSU said that since the specifications were in line with WHO requirements the CPSU opposed cancellation of the tender.

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

This Board,

Having noted this 'Call for Remedy Prior to Closing Date of Call for Competition' filed by Cherubino Limited (herein after referred to as the Appellants) on 6 May 2019, refers to the claims made by the same Appellants with regard to the Tender of reference CT 2056/2019 listed as case no 1324 in the records of the Public Contracts Review Board.

Appearing for the Appellants: Dr Vincent Galea

Dr Francis Basile Cherubino

Appearing for the Contracting Authority: Dr Marco Woods

Appearing for the Department of Contracts: Dr Franco Agius

Whereby, the Appellants contend that:

a) **The Authority, instead of following the World Health Orgainisation recommendations in their entirety, has instead attributed bits and pieces of such recommendations in the technical specifications and by doing so, it has restricted completely the scope of competition. In this regard, Appellants maintain that, the way such technical specifications are stipulated, only one supplier can participate in this tender, whilst there are other suppliers who can offer exactly the same product that meets the international requirement in this field of medicine.**

This Board also noted the Contracting Authority's 'Letter of Reply' dated 31 May 2019 and its verbal submissions during the hearing held on 25 June 2019, in that:

a) **the Authority maintains that, the specifications were formulated on previous procurement requirements which, in turn conform with World Health Orgainisation recommendations of 2010. At the same instance, the specifications for diphtheria component in the 6 in 1 vaccine are the same as those currently in use, to ensure continuity of same treatment.**

This same Board also noted the testimony of the witnesses namely;

Dr Tanya Formosa – duly summoned by Cherubino Limited

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

Dr Salvatore Parisi – duly summoned by Cherubino Limited.

This Board has also taken note of the documents submitted by Dr Parisi which consisted of:

Doc 1 – Hexavent Vaccine Market Study

Doc 2 – Table of Measurement Requirements

Doc 3 – Document Showing Vaccine Characteristics

Doc 4 – Document showing Product Characteristics

and

Document (marked as doc 5) tabled by Dr Franco Agius which consisted of information sheet on Diphtheria Vaccines issue by World Health Organisation.

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 technical witnesses, the latter of which has been given substantial weighting in the decision of this Board, opines that the two main issues that merit consideration are:

a) limitation of competition and

b) compatibility of other related products available on the market

1. **First and foremost, this Board would emphasize that since this call for remedy involves medical vaccines of a highly technical nature, great consideration was taken on the testimony of the technical medical witnesses duly summoned. At the same instance, this Board takes into consideration, as a priority, the treatment and well-being of the patient.**
2. **From the submissions made, this Board was made aware that the Government of Malta had to change from 5 plus 1 to 6 in 1 due to the fact that, the Hepatitis B vaccine was becoming scarce and not freely available and by changing to 6 in 1, the least possible risk is being pursued. In all respects, one has to acknowledge that any changes to the vaccine should not present a risk to the patient.**
3. **One has to consider also the fact that such a procurement involves public funds so that public procurement practice has to be respected and adhered to, so that, the public tender should not be formulated so as to limit competition and in this respect, other prospective competing Bidders has to be given the opportunity to submit their offers, as long**

as their product is compatible with the existing treatment and in no particular way, can inflict negative effects on the patient's treatment.

4. **<u>Limitation to Competitive Participation</u>**

Appellants' contention refers to the fact that their product was in conformity with World Health Organisation specifications and also meets international standards. In this respect, this Board was made aware that switching between products was possible without increasing dosage but, at present, there is insufficient data available to support interchangeable of products from different manufactures. At the same instance, this Board notes that the technical specifications dictated a way of measuring the added antigens in a particular way which, might give the impression that, it is the only method of measure whilst, in actual fact, according to the World Health Organisation, there are other measures equally effective and in this regard, an extract from the testimony of Dr Salvatore Parisi, will highlight such a fact.

"Witness : Yes, not only regarding diphtheria but also regarding antigens. What I am used to see for tender specification, is usually that you find that you ask for a product that is indicated against the immunization of and you list all the disease. Because World

Health Orgainisation gives standards of measuring the quantity of the antigens that are let us say larger than how are described here. Because here how can we see, you basically refer to a product that uses way of measuring the added antigens in a peculiar way. But if you go through the World Health Organisation technical paper of vaccines, you see that there are different way of measuring the quantity of antigens that should be included in the paediatric vaccines and for instance, regarding diphtheria, you find that the quantity that should be included within the vaccine should be not less than 30 international units for diphtheria as a median but then you can use a different methods of measuring the quality test, that is the lower limit of the 95% confidence interval. I know this is very technical but basically if you through this test of WHO it says that in the case you use this lower limit, the quantity that should be at least included is the 50% of the reference. So, the reference is 30. Then the list, it is 15 and if you I can show you a publication that is available

Chairman : *So, in other words, the World Health Organisation does in fact state that you can use other methods of measurement*

Witness : *Exactly*

Chairman : *And it does state as well, the other measurements, the minimum and medical terms*

Witness : *The lower limit of the 95% confidence interval that has to be at least the 50% of the reference. So, the 50% of 30 is 15 in the case of Hexaxim by Sanofi Pasteur it is 20. And even the third Hexavalent vaccine use this method to measure."*

This Board also notes the testimony of Dr Victoria Farrugia Sant'Angelo, which confirmed that there are other measures, as follows:

"Avukat : *Are there any other means in terms of which that particular measurement can be satisfied?*

Xhud : *other means you mean units?*

Avukat : *Yes*

Xhud : *World Health Organisation uses international units or flocculation units LF. What we know is that in older times, the units used to be flocculation units for certain measurement, toxoids.*

Avukat : *So there are other measurements*

Xhud : *It is the unit really of measurement, like you are saying inches or centimetres. Now standards have converted flocculation units into international units so that it will be standard all over the world and 25 flocculation units is equivalent to 30 IU. 25LF = 30IU.*

Avukat : *I wish to forward the witness with the document presented by the appellant Sanofi Pasteur and in particular to the statement where they say that World Health Organisation's standards are fully respected by Sanofi in the production and formulation of its vaccines, including Hexaxime.*

Avukat : *Gol-istess IU naqblu li hemm, nistghu nikkonfermaw li barra li hemm l-international unit hemm equivalent compatible ghalih gol-istess IU?*

Xhud : *Iva. These are confidence intervals which means that the lowest confidence interval is the lowest concentration you can have which will give you 95% confidence that you are producing immunity. So, World Health Organisation gives 30 as the standard. But you can vary. That is the median. But you can vary in between, either a little less or a little more. But 30 being the standard."*

On a concluding note, this Board can safely establish that there are other measurements to establish 'Confidence Intervals', yet the tender document restricts the measurements to 'IU' only and in this respect, a restriction is being created to other prospective Bidders from participating in this procurement process.

5. <u>Compatibility of other Products Available</u>

From the submissions made by the medical technical witnesses, this Board was made aware of the whole immunisation procedure and was also informed that within the 'Primary Course' of the treatment, switching from one product to another does not render the desired effect, however, it has been confirmed by both parties that, after the primary course, a switch to other products having identical specifications, can be applied. In this regard, this Board would refer to an extract from the testimony of Dr Farrugia Sant'Angelo, as follows:

"Avukat : *So you are confirming here that with the specified specs in the tender document, you will be capable of switching on from the 5 plus 1 to the 6 in 1. Would that be possible with products which have different specifications? Say a lower antigen for diphtheria?*

Xhud : *There are no studies which show that they can be effective. In fact, the results so far show that if you are going to switch from one product to the other, you have to start the course all over again. The primary course you should not switch*

Chairman : *The primary course is when?*

Xhud : *The two months, three months, four months*

Chairman : *So we established that the first four months, once you start with a particular product, you have to keep on going until 4 months*

Xhud : *Yes*

Avukat : *With products having identical specs you can switch on*

Xhud : *Yes. But with products having different specs. At two months you can start with the five plus one. At three months, when the next dose is due, you can switch to the six in one, but with the same specifications. That you can do. But if you are going to switch to a different product with different specifications, with less antigen for diphtheria, then in that case you have to start from the beginning. And you need another three (3) doses. As if you are starting afresh."*

After having taken into consideration the testimony of the witnesses, this Board establishes that other different products can be applied either from the beginning of the immunisation treatment or after the primary course, i.e. after four (4) months of the process, using other products.

In this regard, this Board notes that the tender document did not provide for such instances.

In conclusion, this Board opines that:

a) **the way the technical specifications were formulated does in fact, restrict participation in the procurement,**

b) **there are other compatible products available on the market, for which provision was not allowed for in the technical specifications,**

c) **it has been established that there are other measuring units to gauge the 'Confidence Interval', for which not provision was made in the technical specifications,**

d) the tender document should also specify when and under what circumstances, the treatment can be switched to other compatible products available on the market.

In view of the above, this Board,

i) directs that the tender be cancelled,

ii) directs that a new tender be issued to include and reflect other compatible products to participate, taking into consideration this Board's findings.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Lawrence Ancilleri Member

11 July 2019