PUBLIC CONTRACTS REVIEW BOARD

Case 2037 – CT2087/2024 – Supplies - Anti-Haemophilia Recombinant Factor VIII Octocog Alfa

30th December 2024

The Board,

Having noted the call for remedies filed by Dr David Gonzi and Dr Sarah Demicoli on behalf of Gonzi & Associates Advocates acting for and on behalf of PAC3 Limited, (hereinafter referred to as the appellant) filed on the 1st July 2024;

Having also noted the letter of reply filed by Dr Leon Camilleri acting for the Central Procurement and Supplies United (hereinafter referred to as the Contracting Authority) and Dr Audrey Marlene Buttigieg Vella (hereinafter referred to as the Department of Contracts) filed on the 8th July 2024;

Having heard and evaluated the testimony of the witness Professor Alexander Gatt (Head of Haematology Department) as summoned by Dr David Gonzi acting for PAC3 Limited;

Having heard and evaluated the testimony of the witness Dr Dustin Balzan (Acting Director of the Directorate of Pharmaceutical Affairs) as summoned by Dr David Gonzi acting for PAC3 Limited;

Having heard and evaluated the testimony of the witness Ms Sara Bonavia (Representative of the Central Procurement and Supplies Unit) as summoned by Dr David Gonzi acting for PAC3 Limited;

Having heard and evaluated the testimony of the witness Professor Allessandro Gringeri (Professor at Milan University) as summoned by Dr David Gonzi acting for PAC3 Limited;

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

Having noted and evaluated the minutes of the Board sitting of the 19th November 2024 hereunder-reproduced.

Minutes

Case 2037 – CT 2087/2024 – Supplies – Anti-Haemophilia Recombinant Factor VIII Octocog Alfa

Call for Remedies prior to the closing date of a Call for Competition

The tender was issued on the 27th May 2024 and the closing date was the 18th July 2024

The estimated value of this tender, excluding VAT, was € 648,000.

On the 1st July 2024 PAC3 Ltd filed an application for remedies prior to the closing date of a call for competition in terms of Regulation 262 pf the Public procurement Regulations.

A deposit of € 3,240 was paid.

On the 19th November 2024 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Mr Keith Grech as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – PAC 3 Ltd

Dr David Gonzi	Legal Representative
Dr Nicola Mattocks	Legal Representative
Mr Philip Pace	Representative
Mr Alberto Ruffini	Representatie (Online)

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative

Interested Party – Drugsales Ltd

Dr Douglas Aquilina	Legal Representative
Mr Andrew Attard Montalto	Representative
Mr Julian Tonna	Representative

Department of Contracts

Dr Audrey M Buttigieg Vella	Legal Representative

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

Dr David Gonzi Legal Representative for PAC 3 Ltd said that the purpose of this appeal was to remedy ambiguities in the tender in question. There are two types of therapies to treat haemophilia – a plasma derived product and a recombinant one. The tender specifications require recombinant factor VIII of which there are various types. The tender refers specifically to Octocog Alfa which is marketed under various product names. The basis for appellant's claim for remedy is that the specifications are ambiguous even after a clarification had been sought and it is not clear if the tender is restricted to Octocog Alfa. The second ambiguity refers to the definition of the actual generation of the product requested as there is no official definition of the generations. If the tender is interpreted as limited solely to the named product then it is limiting competition as there are other products which provide the same function. There is lack of competition if procurement is limited to Octocog Alfa as the European Medicines Authority (EMA) looks upon the range as one class with equivalent outcomes.

Dr Alexia Farrugia Zrinzo Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that the alleged ambiguity has to be proven by the party alleging it. There are no discriminatory articles in the tender and in any case Public Procurement Regulation (PPR) 53(8) justifies discrimination as justified by subject matter of the contract.

Dr Gonzi mentioned that PCRB Case 1028 was similar to this case. He then requested that witnesses be heard.

Professor Alexander Gatt (152972M) called to testify by the appellant stated on oath that he was the Head of the Haematology Department and defined what recombinant products are and the process

in their production. The first generation contained human plasma which could lead to infections whilst subsequent generations removed human albumen. Apart from generation one, all other generations fulfil the requirements. The procurement in question is for one particular patient and a multitude of recombinant compounds would not be suitable in this particular case as treatment is limited to full length factor VIII molecule. There are presently around twenty haemophilia patients being given plasma derived VIII factor, A general tender for other types of recombinants could be used. The estimated units indicated in the tender does not cover treatment for just more than one person.

Dr Douglas Aquilina Legal Representative for Drugsales Ltd said that to his knowledge the tender is specific to one particular patient and he is aware that there are two different suppliers of Octocog Alfa.

Dr Dustin Balzan (229882M) called to testify by the appellant stated on oath that he is a Pharmacist by profession and currently Acting Director of the Directorate of Pharmaceutical Affairs. Witness was not involved in the drafting of the tender and said that the EMA does nor provide a definition of the different generations which can be interchangeable with no distinction between second or third generation. The tender was issued on the recommendation of the Board of specialist medical staff. In this case there is a difference between general treatment and the specific need of treating one particular patient. Procurement was authorised by the specific Exceptional Committee. The tender does not consider changeability as it is specific to one patient.

Questioned by Dr Farrugia Zrinzo witness stated that the role of the Exceptional Committee is to receive requests for special procurements. The tender specifications detailed by the specialist, Professor Gatt, would have been done in consultation with the consultant monitoring the patient.

In reply to a question from Dr Aquilina, witness said that the scope of the treatment is to ensure that the patient's condition remains stable.

Ms Sara Bonavia (259092M) called to testify by the appellant stated on oath that she issued the tender based on specifications presented by the clinicians but agreed that there is no indication in the dossier that it covered treatment for only one person or that the clarification issued mentions this point. Witness has no knowledge of the technical aspects of the tender or of the product. The replies to the clarifications sought by the appellant were drafted by others and not the witness personally.

In reply to a question by Dr Farrugia Zrinzo, witness said that her role as tender co-ordinator was to ensure that the process was correctly carried out.

Professor Alessandro Gringeri (Italian ID CA 76844PP) called to testify by the Appellant and under oath said that among other qualification and vast experience as a Haematologist he was a Professor at the University of Milan. He stated that there is no official definition by the EMA agencies of second or third recombinant generations – the definition is mainly a marketing issue by the manufacturers. There is no evidence that there is an issue to patients in switching recombinant products as they have the same efficacy and safety – the fourth generation is not an exact definition. Only first generation product can be clearly identified and one should not be distracted by the name as subsequent products have no clear definition as they are all the same class and can be used to treat all conditions.

In reply to questions from Dr Farrugia Zrinzo, witness stated that he had not read, nor was familiar with the tender document. Without the necessary information it would be difficult to decide how many patients the tender covered but certain information can be assumed to make a calculation.

This concluded the testimonies.

Dr Gonzi said that the remedy sought is on the level of ambiguity. The fact is, is the tender limited to Octocog Alfa or not? The specific and detailed clarification sought was answered in very generic terms and referred to the EMA database. The latter groups as a class all Octocog Alfa types. The reply by the CPSU mentioning that other products are excluded is therefore unfounded. The second ambiguity is the reference to generation – there is no definition at official level of generation. Professor Gringeri, in his testimony, mentions that there are full length products that are fourth generation which would be eliminated from this tender – this creates lack of clarity as to what is being requested.

The tender also discriminates, continued Dr Gonzi, as other products such as newer, later versions of Octocog Alfa are excluded. Professor Gatt in his testimony stated that had this tender not been for one patient the product would have been widened as Octocog Alfa can be switched to another type without repercussions since later products such as fourth generation have an advantage on previous ones as they reduce the time needed to administer. Generally different products are functionally equivalent and generally switchable. There is no indication that the tender is catering only for one patient and merely pointing out to the quantity of units is no way to determine that the tender is limited. In the 2016 tender the facts were different – there was no issue of ambiguity and the specifications and criteria were different. There is nothing in the tender to bind the authorities to treating only one patient and this should have been clearly and specifically stated.

Dr Farrugia Zrinzo said that the witnesses heard indicated the basis of the tender requirements. Professor Gatt confirmed that only first generation products can be identified - all following generations are similar. There is a clinical reason for the choice of product and the idea of publishing a tender was to encourage competition. The clarification of the 24th June 2024 asks how many patients are eligible not how many make use of it. If appellant was not satisfied with the reply it could have sought further clarification. Professor Gringeri, who did not see the tender, stated that there are different products but one must respect the patients requirements. In PCRB cases 1833, 1834 and 1835 it was stated that there are limitations to competition whilst in case 1028 the Board stated that the most suitable and safe medication was of a specific type.

Dr Gonzi, in a concluding remark mentioned that further clarifications were not possible because of the time factor.

There being no further submissions the Chairman thanked the parties and declared the hearing closed.

End of Minutes

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Hereby resolves:

The Board refers to the minutes of the Board sitting of the 19th November 2024.

Having noted the call for remedies filed by PAC3 Limited (hereinafter referred to as the Appellant) on 1st July 2024, refers to the claims made by the same Appellant with regard to the tender of reference CT2087/2024 listed as case No. 2037 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr David Gonzi & Dr Nicola Mattocks
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo
Appearing for the Department of Contracts:	Dr Audrey Marlene Buttigieg Vella
Appearing for the Interested Party:	Dr Douglas Aquilina

Whereby, the Appellant contends that:

a) ***Ambiguous Technical Specifications -***

Applicant is concerned with the Tender's technical specifications, particularly the requirement for the products, that is Factor VIIIs to be within the range of the "second or third generation recombinant factor VIII octocog alfa", a mandatory requirement in the Tender. This raises concern as the classification of recombinant Factor VIIIs (hereinafter referred to as "rFVIII") into generations is not an official classification resulting in various sources using different classifications. In fact, it is noted that the European Medicines Agencies has distinguished between two classes of Factor VIII products: plasma derived and recombinant. However, it lacks to provide an official classification per generation. This leaves the technical specifications requiring mandatorily only second and third generation rF VIII octocog alfa unclear and ambiguous since such classification is clearly not well defined or official. Notably, many sources list first-generation, third-generation and innovative third-generation rFVIII with a range of products falling within the innovative third generation list. However, it is unclear whether such products, that is those classified as innovative third generation, would fall within the technical specifications of the Tender. Reference is made to the Clarification Notes issued which rather than clarifying the position, have raised more concerns due to the vague replies provided by referring to the EMA database:

Clarification Note 1 and Note 2 answers: Answer No 1: According to the European Medicines Agency (EMA) database, there are more than one brands of octocog alfa.

As previously noted, the EMA database does not distinguish between different generations of the rFVIII product. On the other hand, the EMA database lists different products under the same

ATC code for the treatment and prophylaxis of bleeding in patients with haemophilia A, compiled using the database of the EMA, as per the Clarification Notes. This database does not distinguish at all between the different generations, but classifies the rFVIII products under the same list. Therefore, the clarifications provided, do not clarify but raise even more concerns as to the products which fall within the specifications required. Moreover, the EMA database also does not properly distinguish between octocog alfa and other rFVIII's, listing all FVIII's under the same class. Hence, it is unjustifiable to limit a call for a specific product type within a class of products, but such call should be a "class" tender without clearly excluding other products which are within the same class. This technical specification is therefore unclear and vague in clear breach of regulation 38 of the Public Procurement Regulations because it is based on a classification which has not yet been officially standardised, is not standard across available means, and opens up for subjective interpretation which may lead to unfair treatment between tenderers.

b) ***Discriminatory Technical Specifications -***

Although the Clarification answers could infer that the technical specifications do not target one or more specific brands, since according to the EMA database there are more than one brands of octocog alfa, this excludes another rFVIII product which is listed by the EMA for the same indications as octocog alfa, which is an rFVIII product. It is noted that both the EMA and even the local Medicines Authority, have issued confirmation that there is no clear and consistent evidence of difference between different Factor VIII products namely recombinant and plasma-derived products. This provides no basis for the Tender to request specifically a particular classification of Factor VIII products over others, as long as the products are essentially providing for the same indications, that is the treatment and prophylaxis of bleeding in patients with haemophilia A. It is therefore, even more concerning that the technical specifications are also distinguishing between second and third generation recombinant Factor VIII octocog alfa products and limiting the tender to products which fall within this ambiguous classification. This limits the selection by excluding all other equally qualifying products.

This Board also noted the Contracting Authority's & Department of Contract's Reasoned Letter of Reply filed on 8th July 2024 and its verbal submission during the hearing held on 19th November 2024, in that:

a) ***On the First Grievance: Ambiguous Technical Specifications***

On the first grievance CPSU and DOC submit that in line with general principles of law, the person who alleges must prove its claim. It is being respectfully submitted that in its application the applicant did not prove any ambiguity.

b) ***On the Second Grievance: Discriminatory Technical Specifications***

CPSU and DOC submit that the applicant's claim that the technical specifications exclude another rFVIII product which is listed by the EMA for the same indications as octocog alfa, is completely

unfounded. CPSU and DOC submit that the above-mentioned product is not on the formulary list and is purchased upon recommendation by the exceptional treatment committee since there is in Malta only one patient on this medication who has been receiving this treatment since the year 2013. The applicant bases its argument on regulation 53(8) of the PPR and quotes part of this sub paragraph. The applicant however conveniently omits the first part of the sub paragraph which states that *"Unless justified by the subject-matter of the contract…"* CPSU and DOC submit that it is necessary the specifications are published as they are due to the condition of the single patient that receives this medication. Moreover, and without prejudice to the above, CPSU and DOC submit that although the tender specifications do place certain limitations to the extent necessary, the same specifications are not limited to one brand only. This has already been explained in the clarification reply. CPSU and DOC rebut this grievance since the conditions stipulated in the tender document are necessary for the medical condition of the patient, as will be further explained in the viva voce testimony.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will now consider Appellant's grievances as follows in their entirety.

a) ***1st grievance - Ambiguous Technical Specifications –***

Various technical explanations were heard and considered (reference to the testimonies under oath of Professor Alexander Gatt, Dr Dustin Balzan and Professor Alessandro Gringeri).

Most importantly, in the opinion of this Board, is that the tender document is making reference to second or third generation recombinant factor VIII octocog alfa. First generation are thereby excluded. This due to their inclusion of human plasma. Therefore, as explained by Professor Gatt, *"all other generations fulfil the requirements"*. This is also corroborated by Professor Gringeri who testified that *"Only first generation product can be clearly identified"*

When considering that this procurement cycle was issued on the recommendation of a board of specialist medical staff and the product is required for the treatment of one particular patient, this Board opines that the technical specifications, as issued, are not ambiguous. This, more so, when one considers that there is more than one product available on the market with the specifications as issued.

b) ***2nd grievance - Discriminatory Technical Specifications –***

One of the main objectives of public procurement is to facilitate the functioning of the market. This is achieved by opening up competition without the interference of any undue limitations.

In fact regulation 53(8) of the Public Procurement Regulations ("PPR") duly states that "……..*technical specifications shall not refer to a specific make or source, or a particular process which characterises the products or services provided by a specific economic operator, or to trade marks, patents, types or a specific origin*

or production with the effect of favouring or eliminating certain undertakings or certain products." However, this regulation also provides for instances and scenarios whereby "*Unless justified by the subject-matter of the contract…..",* therefore implying that on an exceptional basis the Contracting Authority might have more leeway in its procurement process.

None-the-less, the Contracting Authority has duly confirmed in Clarification Note 1 that *"Specs are not brand specific. According to the European Medicines Agency (EMA) database, there are more than one brands of octocog alfa."* Therefore, the relevance of regulation 53(8), in the opinion of this Board, are not at all relevant.

The fact that a Contracting Authority publishes a tender document and not all the products on the market are eligible to meet the technical specifications does not necessarily mean that competition is being obstructed. Contracting Authorities are at the end of the day allowed to procure what goods and services they require. This with the proviso that the procurement cycle has to be in full adherence to the PPR.

Reference is now made to the testimonies under oath of Professor Alexander Gatt and Dr Dustin Balzan whereby it was ascertained that this procurement procedure was also vetted by a board of specialist medical personnel.

Thereby, when considering all of the above, this Board opines that competition is not being restricted and the technical specifications are not discriminatory in nature as is being alleged by the appellant.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

a) Not to uphold Appellant's reasoned application and contentions;
b) That the technical specifications are not ambiguous, unclear and not in violation of the principles of competition;
c) Upholds the technical specifications as issued by the Contracting Authority;
d) In terms of Regulation 267 of the PPR, the closing date of the Call for Tenders to be revised by the Contracting Authority is now the 6th February 2025;
e) Directs that once it was ascertained that this procurement procedure is targeting one patient and this was not made abundantly clear, that the deposit be refunded to the Appellant.

Mr Kenneth Swain	**Mr Keith Victor Grech**	**Mr Lawrence Ancilleri**
Chairman	**Member**	**Member**