PUBLIC CONTRACTS REVIEW BOARD

Case 1641 – RfP 021-6033/21 – Negotiated Procedure for the Supply of Nivolumab 10mg/ml Vials (the Contract)

5th November 2021

The Board,

Having noted the application for ineffectiveness filed by Dr Clement Mifsud-Bonnici, Dr Antoine Cremona and Dr Calvin Calleja on behalf of Ganado Advocates acting for and on behalf of Associated Drug Company Ltd, (hereinafter referred to as the appellant) filed on the 13th September 2021;

Having also noted the letter of reply filed by Dr Alexia J. Farrugia Zrinzo and Dr Leon Camilleri acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 4th October 2021;

Having also noted the letter of reply filed by Dr Steve Decesare and Dr Krista Ellul on behalf of Camilleri Preziosi Advocates acting for and on behalf of A.M Mangion Ltd (hereinafter referred to as the Contract Beneficiary) filed on the 4th October 2021;

Having heard and evaluated the testimony of the witness Dr Alison Anastasi (Head of Operations, Procurement at CPSU) as summoned by Dr Clement Mifsud-Bonnici acting for the appellant.

Having heard and evaluated the testimony of the witness Professor Nick Refalo (Chairman of SAMOC & Clinical Oncologist – Health Department) as summoned by Dr Clement Mifsud-Bonnici acting for the appellant.

Having heard and evaluated the testimony of the witness Ms Jacqueline Gili (Director of Operations at the Department of Contracts) as summoned by Dr Clement Mifsud-Bonnici acting for the appellant.

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

Having noted and evaluated the minutes of the Board sitting of the 21st October 2021 hereunder-reproduced.

Minutes

Case 1641–RfP 021-6033/21. Negotiated Procedure for the Supply of Nivolumab 10mg/ml vials (The Contract)

Application to declare the Contract Ineffective in terms of Regulation 277 of the Public Procurement Regulations

The tender was published on the 6th March 2018.

On the 13th September 2021 Associated Drug Co Ltd filed an application against the Central Procurement and Supplies Unit as the Contracting Authority and A.M.Mangion Ltd as the Contract beneficiary to declare the Contract ineffective in terms of Regulation 277 of the Public Procurement Regulations (PPR)

On 21st October 2021 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Mr Lawrence Ancilleri and Dr Vincent Micallef as members convened a public virtual hearing to consider the application.

The attendance for this public hearing was as follows:

Appellant/ Claimant – Associated Drug Company Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Dr Antoine Cremona	Legal Representative
Dr Calvin Calleja	Legal Representative
Mr David Caruana	Representative
Mr Andreas Yerasimou	Representative

Contracting Authority – Central Procurement and Supplies Unit

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

Preferred Bidder – A.M.Mangion Ltd

Dr Steve Decesare	Legal Representative
Dr Krista Ellul	Legal Representative
Mr Jonathan Mangion	Representative
Mr Ray Vella	Representative
Mr Roger Aquilina	Representative
Mr Marcin Brudnicki	Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties. He noted that since this was a virtual meeting all the parties agreed to treat it as a normal hearing of the Board in line with Article 89 of the Public Procurement Regulations. He then stated that since Cases 021-6033/21 (referred to as 6033) and 021-6034/21 (6034) were very similar in contents unless there were any objections by any one of the parties it was the Board's intention to have the submissions and depositions to apply to both cases.

Dr Clement Mifsud Bonnici Legal Representative for Allied Drug Co Ltd said that there was communality in the two applications and submissions he agreed with the suggestion.

Dr Steve Decesare Legal Representative for A M Mangion Ltd agreed with the suggestion.

Dr Alexia Farrugia Zrinzo Legal Representative for the Central Procurement and Supplies Unit (CPSU) had no objections.

The Chairman noted that the CPSU had put two preliminary pleas on each case which were quite similar.

Dr Mifsud Bonnici suggested that the pleas raised by the Contracting Authority are dealt with the merits and for expediency to deal with the process of hearing the testimonies first and then proceed to the pleas.

The claimant has put in three demands in the application, namely: the ineffectiveness of the Contract, the imposition of a penalty and compensation for actual damages and the Beneficiary has raised a complex point regarding the sensitiveness of the information in the Contract. He was therefore suggesting that the Board deals with the first two claims today and leave the claim for damages till later if the Board agrees that the contract is ineffective.

Dr Zrinzo had no objections to hearing the case in full but the Board is dealing with two separate contracts and on different basis and it was necessary to distinguish between them.

Dr Decesare said that on the preliminary pleas he defers to the wishes of the Authority since they raised the point and agrees that they are heard jointly.

The Chairman proposed a short recess to enable the Board to consider the points raised.

After the recess the Chairman said that the Board had decided that due to the sensitiveness of the case at hand it will deal separately and independently with the preliminary pleas and has taken note of Dr Farrugia Zrinzo's submission in this respect. Therefore the parties are directed to deal with case 6033/21 on its own.

Dr Farrugia Zrinzo stated that the Public Procurement Regulations lay down the situation and timing when an application for ineffectiveness can be filed. The first remedy being sought is exceptional and draconian and the law specifies limited grounds under which it may be filed – these grounds do not exist in this case and the application should be dismissed. The three situations allowed at law in which a case can be filed do not subsist because the Authority was duly authorised to proceed with direct negotiations and the award was properly carried out. The request in 6033 for participation in the 2018 procedure was duly advertised and the contract signed and hence the request for declaration of ineffectiveness is inadmissible.

As regard the preliminary plea regarding the time frame the law defines the period for filing such application which has been exceeded and which cannot be extended in any way – since the contract was signed around September 2018 the claim is outside the period allowed.

Dr Decesare reserved the right to reply.

Dr Mifsud Bonnici said that the pleas raised by the Contracting Authority were difficult to follow and understand. The first pleas which applies to both cases is that the application is inadmissible; that is, that the application is inadmissible if the Authority is right in that it had found one of the limited grounds at law on which negotiated procedure without pre-publication could have been issued. The contention is that there is no such ground and it is inconsistent as there are different grounds to justify the negotiated procedure. One has to hear witnesses to find out what the grounds are. There are differences between the two cases and it does not make sense to link the cases as the negotiating procedure cannot be linked to the 2018 contract – the contention is that they are not linked.

Although in the words of the Authority these measures are extreme and draconian the remedy is there to stop the Authority from breaching the law by issuing contracts outside the proper procedures. From the limited information available this is extraneous in case 6033 whilst in 6034 one must hear witnesses to be able to make a judgement. Appellant has made allegations that the process has not

been followed. On these allegations the Authority's two grounds of absence of competition and urgency are conflicting and it is up to them to show that these grounds exist.

On the second plea relating to the limitation period there is a distinction between the two cases – this contention now is that it is a new contract with new terms and not an extension - if we assume that it is an extension then the limitation period is six months from the date of the signing. The Claimant obtained the information from the Government Gazette as the Authority refused his request for this information but published it the following day; therefore, the limitation is the six month period from the signing of the contract which is taken as the date that it appeared in the Gazette. It is a vexatious argument to claim that the direct order was known to the Claimant through market hearsay and the argument that the information was in the public domain is not sustainable. The standard is the need to publish it in the European Journal or instead by a direct notification through a circular from the Chief Medical Officer. Before the publication in the Government Gazette the Appellant did not have the necessary information to enable it to exercise the remedy under Regulation 277 and was not in a position to exercise such remedy.

Dr Antoine Cremona Legal Representative for Associated Drug Co Ltd said that there are two issues on two different cases with both preliminary pleas and merits and it was not efficient to distinguish between the preliminary pleas and the possibility of spill over into merits. He therefore requested that the preliminary please be heard on both cases. This point was reinforced by Dr Mifsud Bonnici who said that in relation to the plea of lack of admissibility on 6034 he will have to ask questions on the merits of the case.

Dr Decesare said that he had no objection to the request that the evidence relates to both cases. In 6033 there was a distinction to be made between particular points on the modification and negotiating procedure of the contract and the distinction between preliminary pleas. Modification of existing contract in 6033 which includes express review clause and allows extension or similar would not make the contract invalid. If used differently by allowing the widening of the treatments that it is used for, then that goes beyond the original contract and therefore 6033 is substantially different from 6034.

The Chairman rules that the preliminary pleas be heard first and the cases treated differently. He then asked for witnesses to be produced.

Dr Alison Anastasi (398380M) called as a witness by Appellant testified on oath that she is the Head of Operations, Procurement at the CPSU. She stated that her involvement in 6033 was as a representative of the CPSU which tender gave approval for second line cancer and skin melanoma. She was aware that there are other treatments for these conditions and mentioned Dostorlimab by name and one other drug not yet imported in Malta. The period of the contract in 6033 was two years with a potential two year extension – the negotiated procedure period is twelve months. The decision to approve Nivolumab was taken by the Policy Department of the Department (CMO as head, DPA, Health Permanent Secretary and the Committees) in consultation with other stake holders and the extension is until a new cycle is issued. The CMO through his officers monitors the situation with regular updates and issues the necessary information.

Witness was not *au fait* with the date when the decision above was taken as she was not personally involved – she was also not aware whether the EPPs system was used or if it had been published in the European Journal. The CPSU asked for a one year extension as there was no price competition and a contract was in place. There are plans to issue the next cycle of competitive tenders but no date as yet as CPSU were waiting on the Health Department.

Dr Anastasi's testimony was at this stage suspended to enable Dr Nick Refalo to testify.

The Chairman noted that not to use up too much of Dr Refalo's limited time, in the case of this witness he would allow questions on both cases.

Dr Nick Refalo called as a witness by Appellant testified on oath that he is the Chairman of SAMOC and for eleven years has been Clinical Oncologist in the Health Department. He gave an explanation on PD1 and PDL1 inhibiters and how they work on the immune system and the difference between first line and second line treatment. Treatment is determined through rigorous trials mainly carried out by the two main bodies the Food & Drug Administration (FDA) and the European Medicines Agency (EMA).

Nivolumab, according to the witness, is approved for an exhaustive list of cases and used in multiple sites mainly in bladder, lung, renal cell cancers and melanoma but it can be used for other cases. Ipilimumab can be used in many sites and combined with Nivolumab can be used for melanoma, renal cell cancer and lung cancer. Pembrolizumab is used primarily in lung cancer as a single drug or in combination with chemotherapy with other cancers. Through trials its use keeps expanding but as it is not on the market in Malta and if used it is sparingly.

Clinicians use up to date data from the results of trials and toxicity in deciding which medication to use – guidelines are usually issued by the National Institute for Health & Care Excellence (NICE) in the UK, the National Comprehensive Cancer Network (NCCN) in the States and European Society for Medical Oncology (ESMO). Witness stated that he has used all three drugs mentioned above which are all excellent, and also Femro. Pembrolizumab is not available in Malta which is a shame. About two years ago witness was consulted about the use of these drugs by the Medical Authorities; he is keen to have all three available as they have different uses.

Questioned by Dr Farrugia Zrinzo witness said that about two years ago it seemed that agreement had been reached to introduce Ipilimumab which at the time was obtainable via the Malta Community Chest Fund but it would be better if it was obtained by the Hospital but he seemed to think that agreement was not achieved due to price – this information was obtained in discussion with the CMO at the time. According to witness Pembrolizumab is extremely useful and it is a shame it is not available. Witness is not aware of the name of the company the Government was negotiating with. It is possible but not recommended to discontinue treatment on a patient before a period of two years.

In reply to a question from Dr Mifsud Bonnici witness stated that he was not personally involved in the negotiations regarding pricing – he was relating only what the office of the CMO had told him.

Ms Jacqueline Gili (308268M) called as a witness by the Appellant testified on oath that she has been the Director of Operations at the Department of Contracts (DoC) for the last eight years. She stated that in regard to 6033 the Department approved the negotiating procedure request from the beginning to the end. She explained the process and went on to say that the Department enquires why a negotiated procedure is required and ensures that the applicable regulations are applied. The general practice is that a negotiated procedure is allowed if there is only one economic operator and then only one approval is given. If more than one approval is requested the general practice is that it is published on the EPPs to help transparency and it is published in the Government Gazette. Normally the DoC relies on the assessment of the Authority in making the decision.

In 6033, said the witness, there was only one approval to conclude the contract – according to the reasons given by the Authority, competition was absent for technical reasons and supplier enjoyed

exclusive rights. The Department did not investigate if these reasons applied but relied on the Authority's explanation and there was no specific reference to the 2018 tender process in the request for a negotiated procedure – the reference is that it is a continuation of treatment and that it is a branded product patented and supplied by only one economic operator via a negotiated agreement. The request document which was for a twelve month period was submitted to the DoC on 24 March 2021 and the approval issued on 25 March 2021 – the conditions imposed were that the supply was absolutely necessary, that it was cost effective value for money, that funds were available and that the Authority obtained budget clearance. Witness claimed that she had to check, as she could not recall, if the application was published on the EPPs and the European Journal.

Questioned by Dr Farrugia Zrinzo witness replied that the EPPs is used in the case of negotiated procedures although the process was still in a transition stage – it was recommended to be used but it was not obligatory in all cases; because of the volume of contracts it was not imposed on the CPSU.

Recalled by the Contracting Authority to give further testimony Dr Anastasi, on oath stated that the Ocotber 2018 contract for PD1 inhibitors was awarded to A M Mangion Ltd for two years with the possibility of a two year extension. The contract initially was for treatment of second line lung cancer and melanoma but other indication were approved and Nivolumab and other licenced uses included but could not recall the details. The contract was issued with a maximum financial price of € 60,000. The supplier of Nivolumab was the only one to achieve this price and thus was awarded the contract, which has been extended for only one year instead of the possible two with no changes to the financial offer.

Questioned by Dr Mifsud Bonnici what the therapeutic indications were in the 6033 product witness replied that it was for second line cancer and melanoma and any issues indicated later. At present the product was being used for other therapeutic treatments as licenced in the SPC. Witness confirmed that this was in line with the contract conditions, but had no documents in hand to substantiate this statement.

The Chairman directed that the witness produces the necessary documents which the Board will need to see.

Proceeding with her testimony Dr Anastasi was referred to documents ADC1 and ADC3, submitted by Appellant's lawyers and particularly to section 1.2 in those two documents – witness agreed that the words "Any indication that is approved and that will be approved, will be treated at same treatment service price awarded within this RFP" were removed in the later version (ADC3) of the RfP.

Witness could not recall the date when the 2018 tender was awarded to A M €Mangion even when September 2018 was suggested to her, neither could she recall that the value was € 4.2 million.

Dr Mifsud Bonnici requested the Board to direct the witness to refer to the contract if necessary by producing it.

The Chairman suspended the testimony while the witness produced the contract.

On resumption witness stated that the contract was signed on 9 May 2019; the delay being due to negotiations on the policy on cycles and numbers. The value was confirmed as 4.2 million with the variation being due to having to cover extra patients outside the first contract – in terms of price there was no change. Asked to provide proof of date of signing and signatures on the contract witness said that the DoC objected to certain details of the contract being divulged.

The Chairman directed that the CPSU is to provide the Board with copies of the date and signatures of the contract.

In reply to questions from Dr Decesare witness confirmed that in the 2018 tender the capping of the treatment was set at € 60,000 per annum per patient and pay per use basis. The tender was not limited in the number of patients – the 35 patients mentioned was an approximation of the number requiring treatment.

Dr Cremona requested that the contract is made available to the Board in full as this was a duty imposed on the Contacting Authority by the Public Procurement Regulations.

There were no further testimonies to be heard on 6033.

The Chairman proposed that the hearing should now move to preliminary pleas on 6034.

Dr Mifsud Bonnici requested that the testimonies heard in 6033 should also apply to this case to avoid duplicting questioning.

Dr Anastasi (398380M) called as a witness by the Appellant testified on oath that the products in procedure 6034 were for first line cancer. The CMO asked CPSU to include renal cell carcinoma. Witness said that she is aware that there is alternative treatment for first lung cancer but not for renal carcinoma. There was no market research on renal cell carcinoma as the policy was laid down by the Policy Department. Market research is done but in this case it was a matter of shifting patients previously treated through the MCCF. For first line lung cancer the treatment is by Pembrolizumab. EPPs was not used in this case because of the urgency but the approval of the DoC was obtained. Witness stated that she was not aware if there was publication of the procedure in the European Journal. The duration of the present contract was for ten months and the Authority was intending to issue a competitive tender originally in February/March 2022 but was awaiting a policy decision.

Ms Jacqueline Gili (308268M) called as a witness by the Appellant stated on oath that on 6034 the DoC had received a request, processed the recommendation and the General Contracts Committee decided whether to grant approval – there was only one phase of approval and the grounds for justification was Regulation 153 (b). The DoC would assume that market research would have been done to justify the Authority stating that competition was absent. The request referred to was made on the 7 April with approval given on 8 April with another approval issued on 12 April superseding the previous one as a correction was necessary. The first application referred to Nivolumab whereas it should have referred to Ipilimumab 5mg vials. The conditions imposed by the DoC was that the requirements were absolutely necessary, value for money and availability of funds. Witness was not aware if the contract was published on the EPPs or on the European Journal.

In reply to a further question witness said that the period of the agreement was ten months and that for both approvals justification was required that the conditions existed for approval.

This was the conclusion of testimonies.

Dr Farrugia Zrinzo said that the application on 6033 is not admissible as detailed in the letter of reply from the Authority and from the testimonies heard. The period allowed by law is exceeded as this is a contract extension and is therefore *fuori termini.* The limited reasons within which an application is admissible are non-existent.

On 6034 the element required to declare an application inadmissible does not exist as the contract was to signed during this period. The date of the application showed it was filed *fuori termini* and well after the thirty days. The law does not specify the formality required in the notice whichever date – April or July – is chosen.

Dr Mifsud Bonnici said that as a preliminary point he would mention that the pleas raised by the Authority are unfounded, redundant and intended to delay proceedings. The issue of 6033 is pure negotiation procedure bearing no legal link to the 2018 RfP. The extension of an existing contract is a simple matter but this is not a simple extension. Witnesses have stated that 6033 is a new contract deviating from the previous RfP. The 2018 contract was for two years with therapeutic reasons and the scope of it – this was extended later on when it was not allowed in the original RfP. All that the Appellant is expecting is to be able to avail themselves of the tender process.

This claim is substantiated by the wording of the RfP and in the two explanations in ADC1 and ADC3 to see the difference in the procedures after the PCRB sitting. The narrow therapeutic treatments were extended and it is therefore anew RfP – otherwise why would CPSU seek the approval of the DoC if it was merely an extension of an existing contract. If it had been a pure extension the contract reference would have remained the same and would not have been published in the Government Gazette. Referring to document ADC2 Dr Mifsud Bonnici said that the Minutes of the PCRB reflect the real state of affairs; the first contract was limited in scope and was reopened by the Authority by negotiating a new contract.

In regard to both 6033 and 6034 the PPR state that negotiating procedures should be resorted to in exceptional cases and should be avoided. . EU law defined the limited grounds and it is up to the Authority to explain the grounds. There is a fundamental inconsistency adopted by the Authority, namely that the application was made because competition was absent but then they made the claim that it was a case of extreme urgency – one wonders which was the real ground. Competition is not absent as indicated in the written submissions and in the testimonies heard and it seems that after reflecting that they could not explain that there was no competition the Authority created a case of urgency. The Board has not heard a shred of proof of any urgency – there is competition existing as evidenced by the 2018 RfP plus the evidence of Dr Anastasi that there is a tender in the pipeline. The Authority misled the DoC in claiming that there is no competition when competition is obvious. In PCRB Cases 1135 and 1127 the principle was upheld that you cannot rely on medicine being protected by a patent to issue a tender for that product but it has to be widened for class or therapeutic indication.

Recital 50 of the 2014 EU Directive regarding negotiating procedures is exceptional in when one can argue that competition does not exist. The Authority confirmed that no market research was done by the CPSU but the DoC expected it to have been done. The legitimate expectation is that the economic operator has the right to participate in a competition. The case by the Authority with regard to the extreme urgency is poorly motivated. Again referring to Recital 50 and the consistent case law in the CJEU the Authority is faced with a situation where when relying on extreme urgency it has to rely on events that are unattributable and not the fault of the Authority – in 6034 there is no explanation of how the pandemic led to urgency; the onus is on the Authority to prove and justify. The Board has been given a different reason to that given by the Authority.

As regard the lapse of the period of limitation 6033 is not an extension and therefore the Authority's argument that this should have been raised in 2018 does not apply because events transpired afterwards when the tender was widened and which did not exist before. The relevance is on the six month period from signing of the contract and there is no other period in the law. On the reference

to time frames in Regulation 282 the point that is obvious is that it was not published and that it requires action by the Authority to inform bidder by a certain specific action such as direct notification. In this case the Government Gazette was the only source of information but there is no obligation to keep oneself up to date with it. The law in 282 a (ii) speaks of tenders and candidates but the Claimant does not fall into either category as he was not invited to compete.

The Authority did not even reply when challenged by direct letter – there was no admission of a contract and claimed confidentiality. There is just a 'maybe' that a tender will be issued – this is not what public procurement is about.

Dr Cremona said that in general it was unbecoming to have to face obstacles from a public authority and then when legal remedies are sought to construct a defence *ex post*.

Dr Decesare said that 6033 followed a tender procedure in 2018 with the treatment for regimen following the SPC but according to witness through a capped amount but uncapped number of patients which however was higher than the estimated number. The contract was for two years with a further two year extension. If the Authority wanted to distort competition all it needed was to extend the 2018 contract but it elected instead to extend for twelve months and therefore competition was foreclosed for a shorter time. All that the actions of the Authority are doing is to give the claimants an earlier opportunity to compete in the tender. In regard to the negotiations without prior call in both 6033 and 6034 there is no recollection that there was any justification of extreme urgency – this was set out in the response in the letter and in the testimony of Ms Gili. The reason stated that there is no absence of competition conflicts as Dr Refalo stated the three drugs are very good and that they are not replicas of each other – his preference was to have the product supplied by claimant but the treatment should not be curtailed but there was no disadvantage in not having all three. Witness Dr Anastasi confirmed that no market consultation had been carried out but this point was neither proved nor disproved, but evidence given that the originating order did not carry market consultation.

Dr Farrugia Zrinzo said that she had nothing to add.

The Chairman thanked the parties for their submissions and cooperation in what turned out to be an extremely long session 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 21st October 2021.

Having noted the application filed by Associated Drug Company Ltd (hereinafter referred to as the Appellant) on 13th September 2021, refers to the claims made by the same Appellant with regards to the tender of reference RfP 021-6033/21 listed as case No. 1641 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Clement Mifsud Bonnici, Dr Antoine Cremona & Dr Calvin Calleja
Appearing for the Contracting Authority:	Dr Alexia Farrugia Zrinzo & Dr Leon Camilleri
Appearing for the Preferred Bidder:	Dr Steve Decesare & Dr Krista Ellul

Whereby, the Contracting Authority's preliminary pleas are based on the following:

a) ***Situations in which the application of ineffectiveness may be filed –*** CPSU preliminarily submits that this application is declared in admissible, since an application of ineffectiveness, may only be filed:

   i. Regulation 277(2) Public Procurement Regulations (PPR) - *"if the authority responsible for the tendering process has awarded a contract without prior publication of a contract notice in the official Journal of the European Union without this being permissible in accordance with Directive 2014/23/EG, Directive 2014/24/E and Directive 2014/25/EC:"* or

   ii. Regulation 277(3)(a) PPR *"when, notwithstanding an appeal is lodged before the Public Contracts Review Board, the authority responsible for the tendering process concludes the contract before a final decision is given by the Public Contracts Review Board; or"*

   iii. Regulation 277(3)(b) PPR *"when the contract is concluded by a contracting authority or the authority responsible for the tendering process before the expiry of the period for the filing of an appeal as provided for in regulation 271."*

   Thus, the Directive and consequently the Public Procurement Regulations, limits the instances to where this exceptional remedy may be availed of. Thus, an application for ineffectiveness may only be filed in three main circumstances. Firstly, where the contracting authority has directly awarded a contract without placing an OJEU advertisement in circumstances where an OJEU advertisement

is required by the legislation. Secondly, where there has been a breach of the rules relating to the standstill period and that breach has denied the supplier an opportunity to challenge the contract award in relation to a separate, earlier breach. Thirdly, where a call-off contract under a framework agreement for goods or services with a value over the EC procurement threshold has been entered into without following the relevant call-off procedures under that framework. Neither of the above-quoted situations are applicable in this case.

So much so, the request for participation for the 2018 procurement cycle was advertised in the OJEU, there were no pending procedures, and the contract was not signed during the period for appeal of the 2018 procurement cycle or in any other period of appeal prescribed by law. It is very important to emphasise that this a continuance of service regulated by an existing contract.

Moreover, even if the contract merit of this procedure is disregarded, in that it is not deemed that this is a continuance of services regulated by an existing contract, this application would still be inadmissible because the award of this contract without publication, was permissible in accordance with article 32 of the Directive 2014/24/EC, transposed in regulation 150 et seq of the Public Procurement Regulations, particularly regulation 153.

b) ***Date when application for ineffectiveness was filed –***

Regulation 282 of the PPR provides:

"Applications for the ineffectiveness of a contract shall be deemed admissible if they are made:

(a) before the expiry of at least thirty calendar days with effect from the day following the date on which:

(i) the authority responsible for the tendering process or the contracting authority published a contract award notice, provided that this notice includes justification of the decision to award the contract without prior publication of a contract notice in the Official Journal of the European Union; or

(ii) the authority responsible for the tendering process or the contracting authority informed the tenderers and candidates concerned of the signing of the contract; and

(b) in any other case before the expiry of a period of at least six months with effect from the day following the date of the signing of the contract."

Primarily with regard to this preliminary plea, CPSU submits that as indicated in the application, the contract for the supply of Nivolumab was awarded to A.M Mangion 'around September 2018'. As stated in the statement of facts of this reply, the 2018 procurement cycle and contract included a clause

which stated that *'Interested Economic Operators must be willing to provide the service for a period of 2 years with an option to extend with a further 2 years'.*

If the applicant felt aggrieved that the CPSU would be entering or had the chance to enter into direct negotiations with A.M. Mangion Ltd, to extend the term of this contract, it had to file for the ineffectiveness of the 2018 contract, within the timeframe specified in Regulation 282 quoted above, given that this agreement is a continuance of the existing 2018 contract. Filing for ineffectiveness now, puts the applicant *fuori termine* when it comes to the time frames established in the above-quoted regulation.

The period specified by these regulations is a peremptory period and may not in any way or for any reason be extended.

This Board, after having examined the relevant documentation to this application and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will consider the Preliminary Pleas, as follows:

a) ***Situations in which the application of ineffectiveness may be filed –***

The Board notes the following:

i) That the Public Procurement Regulations ("PPR") are very specific in regulations 277(2), 277(3)(a) and 277(3)(b) in listing the grounds permissible for an Application of Ineffectiveness.

ii) That this Board outright notes that regulations 277(3)(a) and 277(3)(b) have not been breached as there were no prior appeals lodged before the Public Contracts Review Board and the signing of the contract was not done before the expiry of the period for the filing of an appeal. These two (2) facts are not being disputed.

iii) That the possible ground for application of ineffectiveness in relation to regulation 277(2) of the PPR needs, however, further delving into.

iv) That the request for participation for the 2018 procurement cycle ("the original contract") was duly advertised in the Official Journal of the European Union ("OJEU").

v) That the original contract's term was for a period of two years with an option for a further two-year extension.

vi) That after the expiration of the initial term (two years), the parties to the contract exercised the option for a one-year extension.

vii) That the extension / option exercised was not for its full term of 'a further 2 years'. Hence the option was exercised for half of its possible total duration.

Therefore, the main issue is to consider whether this 'extension' / 'option' which was exercised, to be deemed as a continuance of service regulated by the existing / 'original' contract or whether the contract has been widened enough to make it to be considered as a new and / or separate procurement cycle.

In relation to above, this Board notes:

i) That the Contracting Authority did not show any 'intent' in distorting competition when it exercised its right for half of its possible duration.

ii) The testimony under oath of Dr Alison Anastasi whereby she stated that the extended period of one year did not involve any changes to the financial offer.

iii) The testimony under oath of Professor Nick Refalo whereby he stated that "*he is keen to have all three available as they have different uses"* (reference to Dostarlimab, Nivolumab and Pembrolizumab). Hence, the Board opines that these medicines are not complete replicas of each other.

iv) The testimony under oath of Ms Jacqueline Gili, representing the Department of Contracts, whereby she stated that *"the Department approved the negotiating procedure request from the beginning to the end"*.

v) Product's, Nivolumab, use is in accordance with the licensed Summary of Product Characteristics ("SPC"). Any changes in use from the original contract are in line with the updated SPC whenever this is approved by the respective Authority.

vi) No other terms of the original contract have been altered.

The Board finally notes that therefore, apart from point (v) above, no other terms of the original contract have been altered and all the PPR procedures in relation to negotiated procedures have been adequately followed by the Contracting Authority. When considering that this treatment is of a very sensitive nature and used in critical healthcare, the wellbeing of the patients receiving this type of treatment is to be considered of paramount importance and should always be the first priority in the decision taken. Therefore, point (v) above is not deemed to constitute a material change and thus, this extension is not deemed to constitute a new and / or separate procurement cycle.

The Board hence upholds the Preliminary Plea as brought forward by the Contracting Authority.

b) ***Date when application for ineffectiveness was filed –***

The Board opines, that due to its decision in point (a) above, it is deeming irrelevant to discuss the date when the application for ineffectiveness should have been filed.

In conclusion this Board;

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

a) To accept the Contracting Authority's first preliminary plea and therefore declare the Application for Ineffectiveness as inadmissible.

Mr Kenneth Swain	**Dr Vincent Micallef**	**Mr Lawrence Ancilleri**
Chairman	**Member**	**Member**