

PUBLIC CONTRACTS REVIEW BOARD

Case 1817 – CT 2256/2022 – Supplies – Tender for the Supply of Radioactive Iodine I-131 Capsules

23rd November 2022

The Board,

Having noted the call for remedies filed by Dr Matthew Paris on behalf of DalliParis Advocates acting for and on behalf of Pharma-Cos Limited, (hereinafter referred to as the appellant) filed on the 12th August 2022;

Having also noted the letter of reply filed by Dr Leon Camilleri acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 17th August 2022;

Having heard and evaluated the testimony of the witness Dr Nicholas Refalo (Chairman of SAMOC & Clinical Oncologist – Health Department) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Mr Fabio Guagnini (Director of GE Healthcare) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Mr Elton Mamo (Representative of Pharma-Cos Limited) as summoned by Dr Matthew Paris acting for Pharma-Cos Limited;

Having heard and evaluated the testimony of the witness Ms Antonia Formosa (Director of Pharmaceutical Affairs – Ministry for Health) as summoned by Dr Leon Camilleri acting for the Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Ms Federica Spiteri Maempel (Representative of Central Procurement and Supplies Unit) as summoned by Dr Leon Camilleri acting for the Central Procurement and Supplies Unit;

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 17th November 2022 hereunder-reproduced.

Minutes

Case 1817 – CT 2256/2022 – Tender for the Supply of Radioactive Iodine I-131 Capsules

Remedy before closing date of call for Competition

LOT 2

The tender was issued on the 24th July 2022 and the closing date was the 30th August 2022. The estimated value of the tender, excluding VAT, for Lot 2 was € 219,780.

On the 12th August 2022 Pharma-Cos Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority seeking a remedy before the closing date of the tender on Lot 2 under Regulation 262.

A deposit of € 1098.90 was paid on this Lot.

On the 17th November 2022 the Public Contracts Review Board composed of Mr Kenneth Swain, as Chairman, Mr Lawrence Ancilleri and Ms Stephanie Scicluna Laiviera as members convened a public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Pharma-Cos Ltd

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| Dr Matthew Paris | Legal Representative |
| Mr Gordon Zammit | Representative |
| Mr Marcel Mifsud | Representative |
| Mr John Soler | Representative (online) |

Contracting Authority – Central Procurement and Supplies Unit

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| Dr Alexia Farrugia Zrinzo | Legal Representative |
| Dr Leon Camilleri | Legal Representative |
| Ms Federica Spiteri Maempel | Member Evaluation Committee |
| Ms Sara Bonavia | Member Evaluation Committee |
| Dr Alison Anastasi | Representative |

Department of Contracts

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| Dr Mark Anthony Debono | Legal Representative |
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Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Matthew Paris Legal Representative for Pharma-Cos Ltd stated that there are two clauses in the tender document which need widening to safeguard competition in line with established jurisprudence. He referred to Section 3 Specifications of the tender item 2.3 stating that the activity should be supplied in one single capsule which is mandatory. However it is also stated that supply of two capsules is allowed if this requirement is not fulfilled. There is no preference indicated – only that in the absence of one capsule alternatives will be accepted. This impinges on the principle of competition. If the Authority is ready to accept two capsules there is no medical reason for preferring one capsule.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit referred the Board to his written submissions and indicated that a witness will explain the reason why one capsule is preferable. The CPSU is entitled to ask for what best fits its requirements.

Dr Nicholas Refalo (512075M) called to testify online by the Appellant stated on oath that he is familiar with the tender dossier. As regard the choice between one or two capsules witness stated that as the pill was radioactive he preferred administering one rather than too many. On practical grounds it made sense to keep it as low as possible.

In reply to questions from Dr Camilleri witness confirmed that from the patient's safety one capsule was preferable. This medication was used in thyroid cancer treatment and is used in hospital under supervision being normally given every six months.

Questioned by Dr Paris witness said that the dose can be administered in any number of capsules but the less capsules that were administered the better. He was not aware who was the supplier of this medication. The high dosage, 7400MBq is not used very often and the lower dosages, 3700 units, are most commonly administered. He presently uses one or two capsules to reach the level required.

Questioned again by Dr Camilleri the witness stated that the more capsules administered the higher the chance of errors – it is better to have as low a number of capsules as possible.

Mr Fabio Guagnini (43032588) called as a witness by the Appellant stated on oath that he is the Medical Director of GE with a commercial relationship with Pharma-Cos who they supply with radioactive single capsules of 5100 units. Two capsules are required to reach the maximum dosage . He does not see any more risk to patients in the number of capsules administered and there is no less efficacy as the final result is the same.

Mr Elton Mamo (111976M) called as a witness by Pharma-Cos Ltd stated on oath that he is that Company's Business Manager and that the firm has been supplying CPSU with this product for some 15 years. The product has always been accepted with no problems. Referred to specific requirement 2.2 of the tender witness said that Pharma-Cos would have no difficulty in meeting it. As far as the requirement on the 740 to 7400MBq range was concerned there was no problem meeting this as GE's product goes up to 5550 units and if a higher dosage is required more than one capsule is used without any ill-effects. The way the tender is worded it is not possible for the economic operator to bid for the higher requirement.

Ms Antonia Formosa (373667M) called to testify by the Authority stated on oath that she is the Director of Pharmaceutical Affairs (DPA) at the Ministry for Health. She said that the tender is complicated and the certification was different from what was approved by the consultants. The specifications by the Directorate is that the treatment can be supplied in maximum two capsules.

In reply to a question from Dr Paris witness replied that the mentioned treatment is approved by medical consultants.

Ms Federica Spiteri Maempel (not stated) called as a witness by the Authority stated on oath that she is a Pharmacist at the CPSU. Referred to the parts of the tender which state either one or two capsules witness stated that this point had not been discussed with Dr Refalo nor was there any correspondence with him on this matter. The specifications had been prepared by the DPA and used in the tender.

This concluded the testimonies.

Dr Paris said that Dr Refalo had stated that either one or two capsules were acceptable and therefore the tender was incorrect in stating 'should be one capsule'. In reality witness Ms Formosa said that the tender was stating the total opposite to the advice given that clinically there was no difference and thus it was incorrect to claim that two capsules were not acceptable for clinical reasons. Witness Mr Mamo had confirmed that Pharma-Cos have been supplying two capsules for 15 years and there was no clinical reason against this. The economic operator wants the tender widened.

As regard the duration the complaint is that the price of a product cannot be hedged for three years without hurting one of the parties and the Authority must accept that there might be changes over a three year period. *Force majeure* creates problems in the market and the Appellant is suggesting a hedge for three year with the opportunity for a yearly revision of prices or shorter contracts with extensions.

Dr Alexia Farrugia Zrinzo Legal Representative for the CPSU said that there are no one year contracts in existence. It is usual for contracts to run for three years as this levels out the risks and expenditure of a shorter contract. The wording in the tender confirms the approval of both versions with preference to the single capsule. Dr Refalo confirmed the risk of more than one capsule and the vulnerability of some of the patients receiving treatment. The acquisition process is one to obtain the best terms and the specification are for wider competition.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 17th November 2022.

Having noted the call for remedies filed by Pharma-Cos Limited (hereinafter referred to as the Appellant) on 12th August 2022, refers to the claims made by the same Appellant with regard to the tender of reference CT2256/2022 listed as case No. 1817 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Matthew Paris

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

Whereby, the Appellant contends that:

- a) ***Condition restricts competition*** - The condition, “*The required activity should be supplied in one single capsule. However, in the eventuality that no economic operator can fulfil this requirement, the government will consider two capsules. Further to this, if no economic operator can supply 2 capsules the government will consider alternative formulations by accepting the increase in the number of capsules to make up the dose.*”, restricts competition, in particular when it clearly stipulates that two [2] capsules shall only be considered, “*in the eventuality that no economic operator can fulfil this requirement*”. Once the contracting authority shall positively, “*... consider two capsules ...*”, it automatically confirms that medically it has no compelling justification to

refuse two capsules instead of one. The manner through which this provision has been drafted restricts competition, since two capsules are only considered if, “... *no economic operator can fulfil this requirement.*”.

It is the humble opinion of the appellant company that, the requirement of Lot 2, breaches Regulation 39(3) of PPR whereby; “*The design of the procurement shall not be made with the intention of excluding it from the scope of these regulations or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.*”

In addition, and in accordance with regulation 53(6) of PPR, the technical specifications should afford equal access of economic operators to the procurement procedure and shall not have the effect of creating unjustified obstacles to the opening up of public procurement to competition.

- b) ***Duration of contract is unfeasible*** - Article 19.1 of the tender document stipulates that the tender duration shall be of 36 months. In a context which is evolving, in a situation which is unprecedented, which situation is also recognized through subsidiary legislation S.L.601.13 [Temporary suspension of certain provisions relating to public procurement regulations] the proposed duration of 36 months is not feasible and creates a difficulty for any economic operator to hedge a price for such a long period.

In view of the above, and in view of the fact that the situation creates uncertainty and excludes competition, the appellant is hereby requesting that the proposed duration is reduced to a more realistic period.

This Board also noted the Contracting Authority’s Reasoned Letter of Reply filed on 12th August 2022 and its verbal submission during the hearing held on 17th November 2022, in that:

- a) Preference to 1 Capsule - The applicant states that the preference to a single capsule restricts competition and that there are no compelling medical reasons to prefer 1 capsule over 2 capsules. CPSU submits that there are reasons of a clinical nature which will be further explained during the sitting why 1 capsule is preferred over 2 capsules of the same dose. Moreover the contracting authority, as a buyer, is entitled to chose (sic) what is best, more advantageous and more practical for it to buy as long as it respects the parameters of the PPR. Moreover, there are various considerations which the contracting authority takes into account when studying specifications for the procurement of any object, in this case a medicinal product, including medical and other legitimate considerations of practicality. Thus, this first grievance is therefore to be rejected.
- b) On the Duration of the Contract - On this particular grievance CPSU initially submits that the terms of 36 months is a maximum duration of the contract, as the contract can be terminated before the said term if the estimated contract value is reached before 36 months. Moreover, CPSU

submits that it is standard practice that a contract has a duration of 36 months, considering that the principal aim of a contract is to offer legal certainty for its duration to both parties to the contract and CPSU, as the procurement arm of the Ministry for Health responsible for the procurement of all state health care services requires a certain level of security of supply for reasonable established durations. It is a well established and widely accepted principle that entities enter into agreement for a particular duration and to ensure supply for that particular duration, with all the risks this may have on both parties. The applicant's argument that the duration is unforeseeable is unfounded and does not hold water - economic operators in various areas of distribution and practice are required to take a calculated risk when entering into an agreement, meaning that the price offered has to factor in all risks. The economic operator has to factor in possible increase in prices, but possible decrease is not to be disregarded and this is the risk that every commercial enterprise takes when entering into an agreement. A risk which CPSU also shares as it is possible that CPSU secures supply for 3 years at a considerably 'high' price and price of supply or transportation might decrease. Such risks which are the basis of commercial activity shall not serve as a reason for the Contracting authority to enter into agreements for durations which are unreasonably short. This second grievance is therefore to be also rejected.

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

- a) ***1st Grievance - Condition restricts competition*** – Reference is made to section 3 of the tender document whereby 'Spec No 2.3' states *"The required activity should be supplied in one single capsule. However, in the eventuality that no economic operator can fulfil this requirement, the government will consider two capsules. Further to this, if no economic operator can supply 2 capsules the government will consider alternative formulations by accepting the increase in the number of capsules to make up the dose"*. It is pertinent to note that this criterion is listed as 'Mandatory', i.e. complete adherence is necessary, otherwise economic operators will be disqualified.

From the current wording of the quote above, it is very much clear that if an economic operator can supply the maximum dose in one (1) capsule and is also fully compliant with all other administrative, technical and financial criteria, than he will be awarded the tender, even if a cheaper bidder would have proposed a two (2) capsule solution, is also fully compliant and submitted a cheaper bid.

From the testimony under oath of a number of witnesses which were produced by the different parties, it can be ascertained that a two (2) capsule solution (to reach the maximum dosage of 7400 MBq), should the need arise, is also medically viable. The only issues, if any, will be those of a logistical and / or practical nature to administer two (2) capsules instead of one (1).

This Board opines, that Public Procurement Regulations are there to protect the interests of open competition. It is also an objective of these regulations to assist Contracting Authorities to acquire services, products or works orders in the most open manner while still upholding the main principles of public procurement.

Therefore, in the opinion of the Board, if the Appellant was proposing a solution that needed a much larger number of capsules, in order to satisfy the required maximum dosage, it would have been acting in an un-proportionate manner.

However, when considering that:

- i. currently there are only two (2) possible suppliers of this product;
- ii. the grievance's the Appellant's main objective is that of 'opening' the specification to include the two (2) capsule solution to be *a pari passu* to the single capsule solution;
- iii. the contracting authority itself, was *ab initio* welcoming a possibility of having and accepting a two (2) capsule solution;
- iv. no proof of a medical nature was presented to ascertain that a one (1) capsule solution is preferable to the two (2) capsule solution; and;
- v. there seems to have been a mis-understanding on the instructions / advice provided by the Director of Pharmaceutical Affairs within the Ministry for Health on what is to be included in the tender dossier

it would be in the interest of open competition that the said specification is to be amended to bring *a pari passu* the two (2) capsule solution to the one (1) capsule solution.

Hence, this Board upholds the Appellant's first grievance.

b) **2nd Grievance - Duration of contract is unfeasible –**

This Board acknowledges that current macro-economic scenario is currently more 'volatile' than what we would normally expect. This due to various reasons which are out of the control of economic operators participating in tendering procedures and also out of the control of the contracting authorities procuring such services, goods or works orders.

In fact, S.L. 601.13 "*Temporary suspension of certain provisions relating to public procurement regulations*" has been issued by the Ministry for Finance.

It is also however pertinent to note that contracting authorities also need to cater for their own specific requirements and as long as all regulations are adhered to, are free to stipulate the term of the tender as per their requirements.

When considering the term of this tender procedure as per paragraph 1.1 of section 1 of the tender dossier, normal praxis of the contracting authority and that no specific proof was forthcoming that this specific product suffers from 'above average' volatility in the market, this Board opines such a provision as drafted in the tender document, is not contravening to the main principles of public procurement.

Therefore, this Board does not uphold the Appellant's second grievance.

The Board,

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

- a) To uphold the Appellant's first grievance on specification 2.3 of Section 3 of the tender dossier (page 20);
- b) Not to uphold Appellant's second grievance;
- c) To order the contracting authority to cancel the current tender procedure and re-issue while also modifying according to the findings of this Board (reference to Specification 2.3 of Section 3 of the tender dossier (page 20) to bring the two (2) capsule solution a pari passu to the one (1) capsule solution);
- d) after taking all due consideration of the circumstances and outcome of this Call for Remedies, directs that the deposit be refunded to the Appellant.

Mr Kenneth Swain
Chairman

Mr Lawrence Ancilleri
Member

Ms Stephanie Scicluna Laiviera
Member