Case 1065 – CFT 021-6059/2017 – Tender for the Supply of Radioactive Iodine 131 Capsules

The Publication Date of the Call for Tenders was 24 January 2017 whilst the Closing Date for Call of Tenders was 13 February 2017. The Estimated Value of the Tender, (Exclusive of VAT) was € 76,750.00.

Three (3) Bidders have submitted offers for this Tender.

On 23 June 2017, Pharma-Cos Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Cherubino Ltd for the price of € 76,750.00 (Exclusive of VAT) against a deposit of € 400.

On 13 July 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Pharma-Cos Ltd

Mr Elton Mamo	Representative
Mr Marcel Mifsud	Representative
Ms Martina Pace	Representative
Ms Maria Chiara Zappala'	Representative
Dr Matthew Pace	Legal Representative

Recommended Bidder – Cherubino Ltd

Dr David Cherubino	Representative
Dr Danica Caruana	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Monica Sammut	Chairperson, Evaluation Board
Ms Federica Spiteri Maempel	Member, Evaluation Board
Mr Adrian Spiteri	Member, Evaluation Board
Dr Stefan Zrinzo Azzopardi	Legal Representative

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd opened by referring to the Letter of Refusal issued by the Central Procurement and Supplies Unit which *inter alia* states that,

"*This Bidder did not submit the Package Insert for the product being offered, as per Article 2 of Section 4 – Technical Specifications of the Tender Dossier*"

He also referred to Clause 2.1 of the Technical Specifications of the Tender Document which states that amongst other things the Bidder had to submit,

"*Mock-Up and Package Insert for product being offered (Applicable for medicinal products excluding "special medicines"*

Dr Paris added that he was finding it difficult whether to advise his clients to file an Objection or not after seeing the Reasoned Letter of Reply issued by the Central Procurement and Supplies Unit on 30 June 2017 but on the other hand the reasons for refusal issued by the Contracting Authority has strengthened their belief that they were right.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether the package insert was the narration which was found inside the package for which Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied in the affirmative.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd added that this was the reason why his clients have filed an Objection. Pharma-Cos Ltd are more than convinced that they have submitted the package insert and with the methodology requested as per Clause 2.1 of the Technical Specifications which *inter alia* said,

"*The following technical documentation is to be submitted online through the prescribed Tender Response Format and by using the Tender Preparation Tool provided*."

If one had to look at the Reasoned Letter of Reply issued by the Central Procurement and Supplies Unit on 30 June 2017, the latter were essentially saying that the package insert was not submitted but at the same time they have annexed Doc 1 which confirms that the package insert was undoubtly submitted.

Dr Paris then referred to the Subsidiary Legislation 458/33, Medicinal Products (Labelling and Packaging) Regulations issued on 30 October 2005 which was a transposition of a directive issued by the European Union. This Legislation makes a distinction between packages and advises on which documents one had to submit with the product. Article 8 of this Regulation gives a definition of every item. His clients were saying that they have submitted the documentation while the Central Procurement and Supplies Unit were saying that the document submitted was a Summary of Product Characteristics.

Dr Matthew Paris added that there was nowhere in neither Local Law nor European Law which defines a package insert. Page 24 of the Tender Document just mentions mock-up and package insert. The Law defines mock-up but not package insert. There are no Legal Terminologies which show this. Such is true that Pharma-Cos Ltd have submitted the package insert that the Central Procurement and Supplies Unit has submitted a proof of this in their reply.

The Appellants' Legal Representative continued by saying that one had also to understand that there should be two types of documents. The Law does not refer to package insert but to package leaflet which was different. The insert is in the package while the leaflet is something different as cited by Article 2 of the Subsidiary Legislation 458.33 issued on 30 October 2005 which *inter alia* states that,

"*Package Leaflet means a leaflet containing information for the user which accompanies the medicinal product*".

The Central Procurement and Supplies Unit have confirmed that they have submitted a Package Leaflet. The Legislation enters into more details which lead us to the argument of substance over form. The Appellants weren't sure whether the Contracting Authority agree that no definition of package insert can be found neither in the Tender Document nor in the Regulations.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd continued by saying that Article 7 of the Subsidiary Legislation 458.33 issued on 30 October 2005 goes into further detail by explaining the contents of the leaflet as follows. He then quoted the first part of this Article which *inter alia* says,

"*The package leaflet shall be drawn up in accordance with the summary of the product characteristics*."

The Appellants' Legal Representative continued by referring to Document 1 of the Reasoned Letter of Reply issued by the Central Procurement and Supplies Unit dated 30 June 2017 which clearly shows the package leaflet. If one had to see how the items were submitted, these were submitted exactly in the order requested by Article 7 of the Subsidiary Legislation 458.33. The Appellants have brought also a person which can explain the contents and further details regarding the matter.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit opened by referring to Clause 2.1 (i) of the Tender Document which said,

"*Summary of Product Characteristics (SPC) of product being offered in one of the official languages of Malta (Applicable for medicinal products excluding "special medicines"*)

Dr Zrinzo Azzopardi continued by saying that the point made by his clients was that Pharma-Cos Ltd has submitted two versions of the Summary of Product Characteristics.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, noted that there was a perversion.

Dr Stefan Zrinzo Azzopardi, the Legal Representative of the Central Procurement and Supplies Unit replied that one should say that there were two different versions. The word "*package insert*" was not there since the technical word was package leaflet but there was a distinction between the Summary of Product Characteristics, Package Insert and what the Regulations mention as Package Leaflet. The Regulation which Dr Paris mentioned was the basis of how a medicine should be registered.

The Central Procurement and Supplies Unit agreed that in order for a product to be registered it must have a Summary of Product Characteristics and a Package Leaflet according to the Regulations. The Tender Document described this as a Package Insert.

It was a known fact that the Document which was submitted satisfied Point 1 whilst the document which was not submitted was the Package Leaflet. There was a difference between one and another since the aim of the Summary of Product Characteristics was different from the aim of the Package Insert.

Dr Stefan Zrinzo Azzopardi continued by saying that if there was a doubt, a Clarification should have been sought. The Tender Document automatically requests two distinguished documents. The basis was the directive which Dr Matthew Paris referred to which makes a clear difference between the two documentations.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether the Package Leaflet was submitted or not.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that if one had to debate the difference between package insert and package leaflet, the Tender Document requested two types of documentation and only one was submitted.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether the information given in the Package Leaflet was the same one given in the Package Insert for which Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied in the negative.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board then asked whether somebody can make a distinction between the two items.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that the difference was that one document was addressed for the chemist or specialist whilst the other was addressed for the consumer. One cannot use a document which had to be used for the specialist and use it for everybody.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd said that the Law refers you to a Document, the Package Insert which was suitable for the professional and another one, the Package Leaflet which was suitable for the patient. Both parties agreed that the Appellants have submitted the package insert and also that the Document presented by the Contracting Authority was brought from the Medicines Authority, which was public. What Dr Zrinzo Azzopardi said in his submission has the market authorisation; hence it was true that this product was on the market.

Dr Paris added that one must not forget the name of this Tender which was "*Tender for the Supply of Radioactive Iodine 131 Capsules*". Whoever read the title is aware that the users of these capsules were specialised. Only persons who were specifically trained can administer these capsules. The Appellants reiterated that what they have submitted, respects Article 7 of the Medicinal Products (Labelling and Packaging) Regulations.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether these capsules are used in hospitals for which Dr Matthew Paris, the Legal Representative of Pharma-Cos Ltd replied in the affirmative.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit added that these capsules have their own particulars.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board then asked whether these can be bought from a Chemist. Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied in the negative.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd added that these are used at a specialised unit.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit added that if one needed these capsules, one had the right to request a document which was not presented. In order to register a medicine, two documents were needed and it seemed that everybody was in agreement that both formats are differently based since these were addressed to different audiences.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether the Package Insert were the instructions to the user for which Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied in the affirmative.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board remarked that in every medicinal bought by the Chemist had to have instructions on how these were to be used. He then asked why the insert was requested if these capsules were not available to be bought from the chemist or taken home.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that the Summary of Product Characteristics, the Mock Up and the Package Insert were requested. The latter referred to the package leaflet. The Medicinal Products (Labelling and Packaging) Regulations, the document which is inserted in the product box is the Package Leaflet. This is mentioned as the Package Insert in the Tender Document. On the other hand, the Summary of Product Characteristics was submitted by Pharma-Cos Ltd while the Package Insert was not.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd countered that this was presented while Mr Marcel Mifsud for the Appellants added that it was to be found in the box.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether the document which explained the side effects and other things was the Summary of Product Characteristics.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd said that if one had to take the Summary of Product Characteristics and compare it exactly with what the Medicinal Products (Labelling and Packaging) Regulations said, it would result that his clients have submitted all the documentation in the exact order of the latter.

Dr Paris added that his clients were the incumbents in a similar Tender so the Central Procurement and Supplies Unit were aware of what was the product submitted. The Package Insert was not a definite one so it does not make sense to exclude Pharma-Cos Ltd when they have submitted the document requested.

At this point, Mr Michael Dalmas, a Pharmacist employed with Pharma-Cos Ltd, the Appellants holding ID Card Number 255464 (M) was summoned by the latter to testify under oath before the Public Contracts Review Board.

Following Mr Dalmas' testimony, Mr Mark Zammit, an Advanced Pharmacy Practicioner within the Central Procurement and Supplies Unit holding ID Card Number 425874 M was summoned by the Contracting Authority to testify under oath before the Public Contracts Review Board

Following Mr Zammit's testimony, Dr Danica Caruana, the Legal Representative for Cherubino Ltd, submitted that many things were mentioned and that the terminologies were getting mixed up. The Package Insert is a particular document which is the Package Leaflet. The latter is based on the Sum of Product Characteristics.

Dr Caruana continued saying that the Witness summoned by the Appellants has confirmed that one of the inserts was the Package Leaflet and everybody knew that they were referring to the same product since Pharma-Cos Ltd frequently submits similar offers for similar Tenders.

Mr Marcel Mifsud for Pharma-Cos Ltd argued that the Package Information Leaflet is not equal to the Package Insert. The latter two items and the Summary of Product Characterisation are all found in the website of the Malta Medicines Authority. When one submits a copy of the Market Authorisation for a product with the Central Procurement and Supplies Unit, this means that the Product is authorised to enter the Market.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Contracting Authority said that the main argument was that the Appellants had a document missing in their submission. There was a reference for the Package Leaflet which was mentioned as the Package Insert. It was evident that there was a difference between what was requested and what was submitted.

Dr Zrinzo Azzopardi continued by saying that it was evident that there was a mistake and therefore the Evaluation Board was correct in discarding Pharma-Cos Ltd's offer. The Legal Notice referred to by Dr Matthew Paris explains how the medicine was to be presented. If there were any doubts, the Appellants should have sought a Clarification.

Dr Matthew Paris, the Legal Representative for Pharma-Cos Ltd submitted that it was absolutely not true that further documents were submitted in this Public Hearing. Any documents submitted were precisely the same like the ones submitted at Tender Stage. The fact that Mr Zammit confirmed in his Testimony that the nomenclature used in Malta was Patient Information Leaflet indicates that they were referring to Article 13 of the Medicinal Products (Labelling and Packaging) Regulations as correctly referred to by the other Witness, Mr Dalmas.

Dr Paris continued by saying that one cannot compare medicinal products since this was a radioactive product. Pharma-Cos Ltd sought their Legal Obligations so that together with the product they give the user the Package Insert. In this case, the user was the professional. If one uses the principle of Substance over Form, the substance submitted was far more than the one requested.

At this stage, the Public Hearing was adjourned to Friday 21 July 2017 at 09:00 wherein the Public Contracts Review Board will transmit the decision taken for this Objection verbally and then distribute a hard copy of the same to all parties concerned.

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This Board,

Having noted this Objection filed by Pharma-Cos Ltd (herein after referred to as the Appellant) on 23 June 2017, refers to the Contentions made by the latter with regards to the award of Tender of Reference CFT 021-6059/17 listed as Case No 1065 in the records of the Public Contracts Review Board, awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellant: Dr Matthew Paris

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellant contends that:

a) **The alleged reason given by the Central Procurement and Supplies Unit for discarding his offer was that Pharma-Cos Ltd did not submit the Package Insert for the product being offered, as per Article 2 of Section 4 – Technical Specifications of the Tender Dossier.**

In this regard, the Appellant maintains that he has submitted all the necessary information for this type of capsule to be administered by

specialists in the field, with particular reference to 2.1 of the Technical Specifications, wherein it was stated that:

"*Mock-Up and Package Insert for product being offered (Applicable for medicinal products excluding special medicines)*"

b) The Appellant also maintains that he has submitted the necessary information in accordance with the Subsidiary Legislation 458/33, Medicinal Products Regulations issued on 30 October 2005 and the contents listed in their submissions following exactly the requirements as requested in the Tender Document.

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 30 June 2017 and its verbal submissions during the Public Hearing held on 13 July 2017, in that:

a) The Central Procurement and Supplies Unit insist that the Tender Dossier requested two distinct documents, namely the "*Package Insert*" and the "*Summary of Product Characteristics*". However, Pharma-Cos Ltd submitted two versions of the "*Summary of Product Characteristics*" but not the "*Package Insert*" and in this regard, the Evaluation Board had no other option but to discard the Appellant's offer;

b) The Central Procurement and Supplies Unit also maintain that the Appellant's contention that he has abided by the "*Subsidiary Legislation 458/33, Medicinal Products Regulations*", has no bearing for the non submission of the requested information, as the quoted Legislation is applicable for the registration of medicine.

This same Board also noted the Testimonies of the witness namely:

1. **Mr Michael Dalmas duly summoned by Pharma-Cos Ltd;**

2. **Mr Mark Zammit duly summoned by the Central Procurement and Supplies Unit.**

This Board has also taken note of the documents submitted by the Central Procurement and Supplies Unit which was a Package Leaflet Information for the User.

This Board, after having considered the merits of this case and after hearing the testimonies of the Technical Witnesses duly summoned by both parties to this Appeal, arrived at the following conclusions:

1. **With regards to Pharma-Cos Ltd's First Contention, this Board, after having heard lengthy submissions both from the interested parties and the Technical Witnesses, first and foremost opines that one has to establish the type of information which was requested in the Tender Document and that submitted by the Appellant.**

   From examination of the relative documentation, the Tender Document requested two documents, namely a "*Package Insert*" and a "*Summary of Product Characteristics*". From the submissions and examination of documentation, it is hereby being credibly established that Pharma-Cos Ltd submitted a "*Detailed Summary of Product Characteristics*" and another copy of the same document in a slightly different form.

   This Board has also justifiably established that the "*Summary of Product Characteristics*" is intended for the use of the medical professional or specialists applying the treatment while the "*Package Insert*" is purely intended for the user, in this case the patient.

   It has been also credibly established that this type of capsule is only applied on patients in hospitals, administered by a highly qualified specialist, so that it has also been asserted that this type of capsule

cannot be purchased or administered by the patient himself and is not available from pharmacies.

The sole purpose of the "*Package Insert*" is for the user to be aware of the type of medicine and its contents. This Board is conscious of the fact that this medical procedure can only be administered in hospitals so that, awareness to the patient of the purpose and use of the same capsule can only be communicated through the specialist applying the latter. This procedure is well known and forms part of the protocol in the medicine field.

In this regard, this Board finds that from the testimonies of the Technical Experts, this capsule can be considered to be a "*Special Medicine*" which in accordance with Clause 2.1 should be exempted for submitting a "*Mock-Up and Package Insert*".

At the same instance, this Board considers that the non-inclusion of a "*Package Insert*" in this particular case, for this type of specialised capsule does not inflict any harm or discomfort to the patient and as the medical treatment is being administered in hospitals only, the patient is pre-advised of the procedure and the effects of such medication.

Needless to mention the fact, that this is not a situation where the patient has to provide for the capsule himself and in reality, the patient relies on the advice and awareness given to him by the specialist.

This Board is by no means eliminating or minimising the importance of the submission of the dictated information in a Tender Document, but rather considering the merits of this particular case in the rejection of the Appellant's offer, in these special circumstances.

This Board, justifiably noted that Pharma-Cos Ltd submitted all the information necessary for the application of this capsule and this same Board also takes into consideration the fact that since the supply and application of the capsule can only be administered in hospital by specialists in the field, the latter is obliged to explain to the patient the use and effects of this capsule, which in most cases, such information is clearer than when one reads the instructions and side effects in a package insert. In this respect, the Appellant submitted the appropriate information for the administrator of this capsule.

At the same instance, this Board is credibly convinced that the non inclusion of the "*Package Insert*" in this particular case and under

these circumstances, will not deprive any rights which the patient has to be aware of the medication he is undergoing as the specialists advice, prior to the administration of this capsule, is sufficient enough for the patient to be fully aware of the effects of the procedure itself.

On the other hand, this Board heard convincingly, from the submissions made by the Technical Witnesses, that enough information was submitted by Pharma-Cos Ltd to enable the applicator of the medical procedure to administer this capsule. It was also clearly stated by the Technical Witness that the capsule package is not given to the patient, so that the latter does not have access to the package and tablet or the insert.

This Board applies the principle of "*Substance over Form*" and "*Proportionality*" and is credibly convinced that the non inclusion of the "*Package Insert*" does not have any bearing effect, neither on the application of this tablet nor on the well being, comfort and safety of the patient. In this regard, this same Board upholds Pharma-Cos Ltd's First Contention.

2. **With regards to Pharma-Cos Ltd's Second Grievance, this Board refers to the Subsidiary Legislation 458/33, Medicinal Products**

Regulations issued on 30 October 2005 and would like to respectfully point out that this legislation, in actual fact refers to the requisites for any type of medicine to be registered and thus can be on the market.

In this regard, this Board opines that it is credibly convinced that the Appellant's product is registered and on the market but the issue at stake is the non-submission of the "*Package Insert*", so that this same Board does not see any relevance to this legislation in this particular case.

However, it is noted that the information given by the Appellant with regards to the "*Summary of Product Characteristics*" conform to the requisites of this Legislation.

3. **On a general note, this Board, in arriving at its deliberations, took great consideration with regards to the Technical Testimonies and also the documentation related to this Appeal. It must be emphasised that in no way, the decisions taken by this Board undermine the importance and obligation which a Bidder should apply in submitting and adhering to the dictated conditions of the Tender.**

However, one must also consider the particular circumstance and the particular reason for a discarded offer. In this respect, this Board,

apart from applying the principles of "*Substance over Form*" and "*Proportionality*" has also considered the practical mode of the application of this capsule, mainly in that, at no time will the package and the capsule will be in the patient's possession, so that the latter's right for information regarding this medical procedure must be forthcoming from the specialist performing such procedure.

In view of the above, this Board finds in favour of Pharma-Cos Ltd and recommends that:

i) **The decision to award the Tender is to be temporarily revoked;**

ii) **Pharma-Cos Ltd's offer is to be reintegrated in the Evaluation Process;**

iii) **The deposit paid by Pharma-Cos Ltd is to be fully refunded.**

Dr Anthony Cassar Chairman	Mr Lawrence Ancilleri Member	Mr Carmel Esposito Member

21 July 2017