

PUBLIC CONTRACTS REVIEW BOARD

Case 1608 – RFP 021-6125/20 – Request for Participation (Negotiated) for Over-labelling Services of Medicinal Products

3rd August 2021

The Board,

Having noted the letter of objection filed by Dr Matthew Brincat on behalf of B&C Advocates acting for and on behalf of Pharmadox Healthcare Ltd, (hereinafter referred to as the appellant) filed on the 17th May 2021;

Having also noted the letter of reply filed by Dr Marco Woods acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 25th May 2021;

Having heard and evaluated the testimony of the witness Dr Richard Despott (member of the Evaluation Committee) as summoned by Dr Marco Woods acting for Central Procurement and Supplies Unit.

Having heard and evaluated the testimony of the witness Mr Keith Frendo (representative of the Appellant company) as summoned by Dr Matthew Brincat acting for Pharmadox Healthcare Ltd.

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 27th July 2021 hereunder-reproduced;

Minutes

Case 1608 – RFP 021-6125/20. Request for Participation (Negotiated) for Over-Labelling Services of Medicinal Products

The RfP was published on the 11th December 2020 and the closing date was the 11th February 2021. The value of the RfP was not stated.

On the 17th May 2021 Pharmadox Healthcare Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that the offer was not technically compliant.

A deposit of € 1,200 was paid.

There were five (5) bidders.

On 27th July 2021 the Public Contracts Review Board (PCRB) composed of Mr Kenneth Swain as Chairman, Dr Vincent Micallef and Mr Richard Matrenza as members convened a public virtual hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellant – Pharmadox Healthcare Ltd

Dr Matthew Brincat	Legal Representative
Mr Keith Frendo	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Dr Richard Despott	Member Evaluation Committee
Mr Hristov Hristo Ivanov	Representative

Preferred Bidders – Medical Logistics Ltd

Dr Karl Tanti	Legal Representative
Ms Samantha Cusens	Representative

- Spectra Ltd

Mr Mark Camilleri	Representative
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- Consolidated Packaging Ltd

Dr Antoine Cremona	Legal Representative
Dr Calvin Calleja	Legal 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 asked Appellant’s representative to make his submissions.

Dr Matthew Brincat Legal Representative for Pharmadox Healthcare Ltd said that the Contracting Authority had disqualified Appellant’s offer on two points. The first point regarded the claim that Appellant lacked the necessary licence – proof of which was not required. Other bidders likewise did not have a licence but were awarded the tender. The general conditions of the tender merely state that the bidder is duly licensed – the process to obtain a licence is lengthy and runs well beyond the period of the tender.

The second point concerns the lead times. The tender lacked clarity on this part and other bidders are complaining about this matter since it is very difficult to estimate price and lead times without knowing the quantity of labels required. The same point applies also in the case of translations were no quantities were specified and therefore Appellant did not fill in the appropriate section.

Dr Woods Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that a witness will be asked to testify in regard to the requirement for a licence. The Public Contracts Review Board (PCRB) policy is that documents have to be submitted at least three days before the hearing as against Appellant’s attempt to present it at the hearing. The lead times are clearly stated in point 1

and 1a of the tender – unfortunately the Appellant’s did not propose the best lead times. The failure to fill the section on translation was not rectifiable as it came under Note 3. The Public Procurement Regulations (PPRs) are very clear on what should happen if certain points in the tender are unclear or ambiguous. Appellant was expecting its bid to win even though sections 1.1b, 2.1b and 3.1b were left blank in its submissions whereas the preferred bidder submitted a complete bid form.

Dr Richard Despott (38068M) called as a witness by the Authority testified on oath that he was one of the evaluators in this tender. He stated that Appellant had not been excluded on the basis of the lack of a licence. Guide lines on volumes had been indicated which contradict Appellant’s claim and that in any case they had the opportunity to seek further clarifications. Regarding time lines bidders were requested to give the maximum guide lines based on worst case scenarios.

In reply to questions from Dr Brincat witness did not agree that the estimated volume of labels was not stated and said that the Evaluation Committee had worked on a worst scenario of 7 days. The bidder had to indicate a maximum time frame (Technical Specifications page 9). The figures given correspond to the guidelines to enable bidders to form their bids.

Dr Karl Tanti Legal Representative for Medical Logistics Ltd said that Appellant now wanted to know certain facts as, for example, quantities that were not part of the tender.

Mr Keith Frendo (537683M) called as a witness by Pharmadox Healthcare Ltd testified under oath that he had been in correspondence with Mr Ivanov of the CPSU from the 11th February to some date in March regarding the licence to handle controlled drugs and had confirmation that he had sent a copy of the licence before submitting tender.

Dr Tanti said that Appellant’s offer of 1 to 7 days is ridiculous as anyone bidding one day would better any offer – the time frame should be on the maximum number of days as confirmed by the CPSU. On the question of the translation costs every bidder had the opportunity of seeking clarification but Appellant seems not to have used it – they cannot now argue that it was not fair.

Dr Brincat said that the tender did not request least times and this was a critical point. The Board should check for themselves what was offered regarding lead times. The cost/lead time ratio should be compared to the quantities required. If facts are not clear the evaluation should be cancelled.

Mr Mark Camilleri Representative for Inspectra Ltd said that his company had the necessary licence so there were no issues with their offer but he had been unable to discover where the register of such licences was held. Regarding time lines and price the tender was clear that the latter was the main criterion as the time lines were not well defined.

Dr Marco Woods said that it must be emphasised that the maximum time line was requested in the tender as borne by the witness and it is difficult to understand how Appellant is claiming otherwise. Although the quantities suggested in the tender were based on average figures used in the past the new offer has to be evaluated on the basis of bids on this tender not on past history. The minimum figure is decided by the offers and not set by the Authority and if there were any doubts clarifications were always available. The Authority disagreed that price is the main criterion as the tender requirements are linked to the time lines. With regard to the technical offer of Pharmadox it was clear that information was lacking and cannot be justified.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 27th July 2021.

Having noted the objection filed by Pharmadox Healthcare Ltd (hereinafter referred to as the Appellant) on 17th May 2021, refers to the claims made by the same Appellant with regards to the tender of reference RFP 021-6125/20 listed as case No. 1608 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Brincat
Appearing for the Contracting Authority:	Dr Marco Woods
Appearing for the Preferred Bidder (Medical Logistics Ltd):	Dr Karl Tanti
Appearing for the Preferred Bidder (Inspectra Ltd):	Mr Mark Camilleri
Appearing for the Interested Party (Consolidated Packaging Ltd):	Dr Calvin Calleja & Dr Antoine Cremona

Whereby, the Appellant contends that:

- a) **Licences-** Inspectra Limited not only do not have the certification, authorisation and the required licences by the Medicines Authority to effect Serialization but rather altogether are restricted and precluded from handling pharmaceutical products falling under the scope of the FMD directive where serialisation is applicable.
- b) **Points 1 & 1.1a –**
 - i. With respect to quoting lead time as 1 to 7 working days cover the different ranges in terms of quantity of the respective batch undergoing secondary packaging and is therefore the minimum one can be expected to be allowed to present requested details in the bid. Lesser than 1 day is close to the impossible. Hence declaring the appellant as non compliant on shorter lead time is unacceptable.
 - ii. Over the last few years to date, CPSU has been engaging Pharmadox for the same activity across numerous products with wide ranging batch sizes and have been commended for the expedited turnaround time and quality of service on numerous occasions by multiple individuals within CPSU.

c) **Points 2, 2.1a, 3 & 3.1a -**

- i. With regards to this disqualification the Appellant submits that the adjudicators should have been aware that Translations are quoted per words and vary as to language and amount of literature involved. To this effect Doc E has been presented that is a separate tender document that specifically refers to Translation services in the pharmaceutical industry. It's a complex and particular assignment depending on the amount of literature and the language. Translations are quoted on amount of words and the language, hence the applicant in the present tender / RfP could not have quoted any translation without knowing the amount of literature involved. As can be attested translation quotes form a separate tender assignment and this is certainly known or should have been known to CPSU.

d) **Points 1.1b, 2.1b & 3.1b -**

- i. Page 11 of the tender document clearly states "*No bids will be rejected for incompletely filled FBF in this case as long as the Filled in Sub Types are clearly indicated also in the Provided Technical Offer*". Therefore the CPSU was irregular when it disqualified appellant for not submitting quote for serialization and this should not have been a disqualification factor.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 25th May 2021 and its verbal submission during the virtual hearing held on 27th July 2021, in that:

- a) **Licences-** With regards to the primary contention raised by Appellant in that they claim that Inspectra Ltd are not in possession of the required licences as issued by the Medicines Authority, it is to be noted that the requirement to submit any certification relevant to licences as issued by the Medicines Authority is not found. Therefore, since the Tender dossier did not include this requirement at this stage, then the preferred bidder could not have been rejected on this ground.

b) **Points 1 & 1.1a -**

- i. CPSU submits that the reasons why their offer for sub types 1 and 1.1a was not accepted is due to the fact that the Recommended Bidder proposed shorter lead times.
- ii. The sole award criterion clearly stated "*the Contract for each respective Works Order sheet will be awarded to the Economic Operator submitting the cheapest offer; **provided that the offer reflects the minimum timelines, which ensure least delay in making the medicinal product available to users within the Government Healthcare Service. In this regard, due consideration will also be given to those applicants who offer tangible advantages in terms of shorter timeframes and overall reduction of logistical delays.***"
- iii. The RfP clearly outlined that the cheapest technically compliant offer will be chosen, provided that the offer reflects the minimum timelines. The fact that CPSU has been

engaging Pharmadox for the same activity across numerous products for which Pharmadox have been commended is irrelevant.

c) **Points 2, 2.1a, 3 & 3.1a -**

- i. CPSU contend that the contract presented by the objectors and attached as 'Doc E' cannot be submitted in order to justify the non-compliance of their offer for the said types as the contract in question refers to a different Tender, which contract was not requested in the requirements in the RfP.
- ii. The reason why the objectors were rejected for these lots was due to the fact that as is evidently clear in the Technical offer form, although indicated on Page 1 of the Technical Offer, the objectors clearly stated **No Translation** for all sub-types 2, 2.1a, 3 and 3.1a.
- iii. It is unacceptable that the objectors claim not to have submitted because they had no indication of the quantities of translation needed or on the number of words to be translated, as the objectors had every opportunity to clarify further whether they needed to submit an offer.
- iv. It is unacceptable for the objectors to claim that the RfP has been wrongly drafted and published, as if the objectors felt that the RfP was ambiguous or that there were wrong / contradictory clauses in the RfP, they ought to have exhausted their remedies as per the Public Procurement Regulations and submitted a Reasoned Application before the Closing Date of a Call for Competition as per Regulation 262 in order to challenge the RfP.

d) **Points 1.1b, 2.1b & 3.1b -**

- i. Objectors were not considered any further for the sole reason that they did not submit any offers with regard to the sub-types. Objectors have wrongly interpreted the clause of page 11 "*No bids will be rejected for incompletely filled FBF in this case as long as the Filled in Sub Types are clearly indicated also in the Provided Technical Offer.*" The objectors did not complete the Technical Offer Form with regard to these sub-types.

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 consider Appellant's grievances, as follows:

- a) **Licences-** reference is made to 'Section 1 – Instruction To Tenderers'. No reference is made to the requirement to submit any certification relevant to licences as issued by the Medicines Authority. Since this is not a specific requirement at this stage, within the Tender dossier, then the preferred bidder (Inspectra Ltd) could not have been treated as non-compliant on this ground.

This Board does not uphold this grievance of the Appellant.

b) Points 1 & 1.1a –

- i. This Board refers to ‘Section 3 – Technical Specifications – Scope of Service’ of the Tender dossier, whereby it is stated *“For each of the Works Order subtype quoted, the applicant should specify the maximum timeframe required to supply each individual service from the date of request”*. Hence if the Appellant provided one (1) range being one (1) to seven (7) days, the Evaluation Committee was right in its assessment to evaluate on the seven (7) days submission. This was confirmed as stated under oath by Dr Richard Despott. Since the preferred bidders indicated a shorter time lead.
- ii. This Board humbly points out that with respect to the Appellant being *“commended for the expedited turnaround time and quality of service on numerous occasions by multiple individuals within CPSU”*, deems this to be irrelevant to the procedures of this particular and specific case.

This Board does not uphold this grievance of the Appellant.

c) Points 2, 2.1a, 3 & 3.1a –With respect to these 4 ‘sub-sections’, this Board notes the following:

- i. ‘Doc E’ as submitted by the Appellant is deemed to be inadmissible and irrelevant since it refers to a different Tender with different specifications and requirements.
- ii. The Appellant’s Technical Offer submission for these sub-sections, which is a Note 3 document, was “No Translation”, which left little room for the Evaluation Committee to manoeuvre. The Evaluation Committee adhered to the policy of ‘Self Limitation’ and did not seek a rectification to this offer.
- iii. The Appellant could have made use of a ‘Request for Clarification’ if it felt the need for further information when formulating their proposal. If on the other hand, their assessment was that the request from the Contracting Authority was ambiguous and that the tender dossier was incorrectly drafted as *“the adjudicators should have been aware that Translations are quoted per words and vary as to language and amount of literature involved”* and *“Translations are quoted on amount of words and the language, hence the applicant in the present tender / RfP could not have quoted any translation without knowing the amount of literature involved. As can be attested translation quotes form a separate tender assignment and this is certainly known or should have been known to CPSU.”*, they could have made use of the remedy as stipulated under Regulation 262 in order to challenge the RfP before the closing date of the call for tender. Regulation 262 (d) of SL 601.03 is specific when it states *“to correct error or to remove ambiguities of a particular term or clause included in a call for competition, in the contract documents, in clarification notes or in any other document relating to the contract award procedure”*.

This Board does not uphold this grievance of the Appellant.

- d) ***Points 1.1b, 2.1b & 3.1b*** – As already pointed out by this Board in point (C) (ii) above, the Evaluation Committee is precluded to ask for rectification of Note 3 documents. In this specific case, for these sub-sections, the Technical Offer was left completely empty. The concept of ‘Self Limitation’ was adhered to by the Evaluation Committee.

This Board does not uphold this grievance of the Appellant.

The Board,

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

- a) Does not uphold Appellant’s Letter of Objection and contentions,
- b) Upholds the Contracting Authority’s decision in the recommendation for the award of the tender,
- c) Directs that the deposit paid by Appellant not to be reimbursed.

Mr Kenneth Swain
Chairman

Dr Vincent Micallef
Member

Mr Richard Matrenza
Member