

PML 05/2015 – CLARIFICATION REQUEST REPLIES

Answers in Purple

Email 1

a). Sub-criteria – Breakdown of points – page 19 - Point 4a. List of Principal Deliveries by the candidate of a pharmaceutical and medical supplies automation nature over the past five years.

Question 1.1 - Could you please clarify if the value stipulated on the left hand side of the table refers to the value per project or of the sum of the projects (the sum of a maximum of five projects)? Also could you please clarify if at least two reference letters are required per project or for all the projects listed in this question?

Answer 1.1 - The points in the column under section 4a are attributed per project up to a maximum score of 30. In respect to the reference letters, two reference letters from any of the five projects mentioned are required.

b). Sub-criteria – Breakdown of points – page 18 - Point 3b. Years of employment in the Pharmaceutical/ medical supplies automation sector and number of projects the employee was involved in.

Question 1.2 - Could you please define the meaning of “ + 1 related project”? Please give examples of related projects that are acceptable for this project.

Answer 1.2 –The +1 related project means that in order to obtain the 2 marks, it is not sufficient only to be employed for 10 years or more in the pharma/med supplies automation sector. The expert must also have been involved in at least one related project , such as but not limited to automation in the stock control and distribution chain and demonstrate it (in the form on page 33). So if a person has been employed for 12 years in the sector but is not able to demonstrate his role in at least one particular project, s/he gets 0 points from this criterion. If, on the other hand, the expert has less than 10 years experience but can demonstrate participation in 5 projects or more, s/he gets the 2 points.

c). Sub-criteria – Breakdown of points – page 17 - Point 1b. Average turnover over the past three financial years from services/supplies/works for the pharmaceutical and medical supplies automation sector.

Question 1.3 - Could you please clarify if the turnover for the supply of both pharmaceutical and medical supplies to the CPSU can be used for this exercise?

Answer 1.3 – Positive, however the economical operator must prove that at least 50% of such turnover is attributed to pharmaceutical and medical supplies whilst another 50% is attributed to automation in the stock control and distribution chain.

d). Insurances – Page 24 – Point 9. Please provide details of the candidate`s: (a) employer`s liability, (b) public liability and (c) professional indemnity insurances.

Question 1.4 - Could you please clarify if a proforma insurance with the required details would suffice for this exercise? The requested policy would be issued at a later stage.

Answer 1.4 – Positive.

e). Form 1 – Page 20 – Point 1. Details of candidate

Question 1.5 - Could you please clarify whose details should be filled in Form 1 if the Candidate is made up of a joint venture? Should we fill in a form for every partner in this joint venture?

Answer 1.5 – No. In form 1 the name of the Candidate should be inserted. So in the case of a joint venture the Candidate (who must always be one) would mean the name given to the JV - for example ABCDE Malta JV. Then the lead partner and the other partners are identified in Form 2 (pg 26). The Candidate will be the official entity.

f). Criterion 1 – Financial Standing - Page 28 – Point (iii) – Please provide the name and address of principal banker together with the banker`s reference.

Question 1.6 - If the candidate is a joint venture should we fill in the banker details for each of the partners?

Answer 1.6 – Positive.

Email 2

Insurances – Page 24 – Please provide details of the Candidate`s (a) employer`s liability, (b) public liability; and (c) professional indemnity insurances.

Question 2.1 - We have contacted a number of Insurance Policy Providers and we require further fundamental information for the Providers to be able to quote. We would like this requirement to be removed from this stage of the tender document and inserted in the next phase of the tender process.

Answer 2.1 – An official declaration from a certified insurance company stating that it would provide the coverage stipulated in the PQQ document should the contract be awarded to your company, is required.

Email 3

Question 3.1 - We refer to your request entitled “**Prequalification Questionnaire (PQQ) for the award of a public service concession for the design, manufacture, delivery, installation, operation, training, maintenance and periodic upgrading of an automated single dose-system and smart cabinets for Pharmaceutical, Medical Materials and Surgical Devices for E-Prescribing and Medicines Administration (ePMA) to the Department of Health (Malta)**”

We respectfully request that, due to the complexity of the project, the deadline for submissions be extended by at least two weeks.

We hope that our request may be acceded to.

Answer 3.1 – The deadline for submissions is extended to Thursday 7th January 2016 at 10:00 am CET. Amended timetable is as follows:

Prequalification Questionnaire (definite timetable) (Stage 1)	Date	Time
Deadline for request for any clarifications from the Administrator	2 nd December 2015	5.00 pm (CET)
Last date on which clarifications are issued by the Administrator	7 th December 2015	5.00 pm (CET)
EXTENDED Deadline for submission of Prequalification Questionnaire	7 th January 2016	10.00 am (CET)
Opening Session of Prequalification Questionnaires	7 th January 2016	10.00 am (CET)
Prequalification Questionnaire Validity Period	7 th April 2016	

Competitive Dialogue (indicative timetable) – Stage 2A	Date	Time
Invitation to Participate in Dialogue	4 th February 2016	
Site visit/s	15 th and 16 th February 2016	
Deadline for submission of initial solutions	1 st March 2016	
Dialogue meetings	Week starting 14 th March 2016	
Shortlisting of initial solutions	24 th March 2016	
Competitive Dialogue (indicative timetable) – Stage 2B	Date	Time
Invitation to participate in Dialogue on detailed solutions	29 th March 2016	

Deadline for submission of detailed solutions	12 th April 2016	
Dialogue meetings	Week starting 25 th April 2016	

Best and Final Offer (indicative timetable) – Stage 3	Date	Time
Publication of document inviting the submission of the Best and Final Offer	30 th May 2016	
Deadline for submission of Best and Final Offer	21 st June 2016	
Notification of award	29 th July 2016	

Email 4

Question 4.1 - Can you please clarify if we can include the turnover of the technology suppliers in the working for the turnover? Specifically, I refer to page 16, subheading 7 and page 17, sub criteria breakdown.

Answer 4.1 - We agree as long as these technology suppliers are confirmed as business partners in the venture through which the company bidding for the tender will be making use of such technologies since there must be evidence of aftersales support given the fact that this agreement will be long term.

Email 5

Question 5.1 - Regarding to the procedure PML/05/2015 and the document FORM 1, POINT 9, we kindly ask to confirm us that, in case the Candidate possesses, at the time of the application, an insurance policy only partially in compliance with the requirements of the aforementioned document (for example, a lower maximum coverage respect to what was requested), the data related to the insurance policy can be inserted in the table, attaching to the declaration, the commitment that, in case the PQQ is awarded, an ad-hoc insurance policy in compliance with the requirements declared by the Authority will be made available.

Answer 5.1 – An official declaration from a certified insurance company stating that it would provide the coverage stipulated in the PQQ document should the contract be awarded to your company, is required.

Email 6

Question 6.1 - Is it necessary to take out a new insurance or are the PQQ requests going to be acquitted, indicating the information of a current company's insurance use?

Answer 6.1 - *Either option would be considered acceptable provided said insurance complies with the requirements of the tender documents.*

Question 6.2 - Must all the insurances be already active by the time of the PQQ presentation, or is it possible to activate them in case if the contract is awarded? In particular, is it possible to declare the commitment to activate it at a later step of the Dialogue instead of submitting the professional indemnity insurance immediately?

Answer 6.2 - *An official declaration from a certified insurance company stating that it would provide the coverage stipulated in the PQQ document should the contract be awarded to your company, is required.*

Question 6.3 - As the participation in the PQQ is open on equal terms to all natural and legal persons of the Member states of the European Union, the beneficiary country and any other third country, in case of consortium, can all the partners be foreign?

Answer 6.3 - *Positive.*

Question 6.4 - In the questions that indicate a maximum number of words permitted for the response (eg Form 1 - Q1 or Q10), does this limit refer to each member or is it total?

Answer 6.4 - *The maximum number of words permitted for the response is for the total.*

Email 7

Question 7.1 - Whether submission can be done as a Joint Venture (JV) and in the case of award the JV can change its legal composition into a Limited Liability Company with same partners on the JV?

Answer 7.1 - *Yes the submission can be made as a Joint Venture with clear indication on the leading party. A joint venture would be allowed to convert into a limited liability company (same participation and composition) provided that all joint venturers guarantee, jointly and severally, the due performance and liabilities of the company.*

Question 7.2.1 - Part 3 Clause 9: Insurances

In the case of Joint Venture will Projects Malta Limited accept that the minimum of Euro 5,000,000 for any one incident is calculated on various policies of the various partners within the Joint Venture as an aggregate?

Answer 7.2.1 - *The Joint Venture will have to declare upfront the leading party which will be legally representing the group in case of any incident. Separate insurance policies are to be issued from the ones already held by the tenderers on their other businesses.*

Question 7.2.2 - Part 3 Clause 9: Insurances

Is it acceptable to get a letter of undertaking from a leading insurance agency in Malta informing the Contracting Authority that they will undertake all the insurance requirements of the Joint Venture as per tender requirements in case the JV is awarded the tender.

Answer 7.2.2 – *Positive. The insurance agency does not need to be located in Malta.*

Question 7.3 - Evaluation Criteria

Are suppliers to a Joint Venture taken into account where Evaluation Criteria is concerned? For example - Page 16 Financial Standing 1b - can a Candidate (Joint Venture) quote statistics from one of its suppliers (not partners)?

Answer 7.3 - *No.*

Email 8

Question 8.1 - Form 4 – No. 10 page 39. A list of the minimum hourly workers` costs involving the provision of the employees` services in this tender is being attached. Could you please clarify what is actually requested in this question?

Answer 8.1 - *The economical operator is to submit the details pertaining to the minimum hourly workers' costs involved in the eventual provision of this service in order to execute this project.*

Question 8.2 - We would like to ask if it would be possible to extend the deadline for the submission of the PQQ to Monday 21st December 2015 @ 10:00 am (CET), in view that only a week would be left from receipt of clarification answers.

Answer 8.2 - *The deadline for submissions is extended to Thursday 7th January 2016 at 10:00 am CET. Refer to Answer 3.1 for amended timetable.*

Email 9

Question 9.1 - In view of the short period to prepare the PQQ an extension be granted to the submission date of the PQQ.

Answer 9.1 - *The deadline for submissions is extended to Thursday 7th January 2016 at 10:00 am CET. Refer to Answer 3.1 for amended timetable.*

Question 9.2 - The diagrams towards the end of the PQQ seems to indicate specific solutions, please confirm that other systems achieving a similar overall solution / end objective would also be considered.

Answer 9.2 - Positive and this was induced just for guidance purpose.

Question 9.3 - PQQ indicates that the concession contractor will be responsible for various logistics and administrative roles apart from the provision of equipment. However points are only allocated for technology systems provision. Once logistics and handling of products and administration of ordering and paying supplier invoices plays a major role, please consider reallocation of points to reflect these important functions.

Answer 9.3 - The points have been allocated as deemed necessary to assess the suitability and robustness of the interested economical operators and these will remain unchanged.

Question 9.4 - Please elaborate the roles and functions of the concession contractor on the ground in Malta, in terms of logistics, handling, distribution and managing the supplies and payments with supplier third parties.

Answer 9.4 - The concession contractor will be responsible to handle all activities and payment will be done to the contractor based on the dispensing to the patient.

Question 9.5 - Is physical presence in Malta required of the concession contractor?

Answer 9.5 - The concessionaire must ensure optimal response at all times within the timeframes that shall eventually be included in the tender conditions.

Question 9.6 - In accordance with local legislation, any party handling pharmaceuticals must have a licensed premises in Malta and be in possession of the required licenses, including a Pharmaceutical Wholesale Dealer License issued from the Malta Medicines Authority to be able to receive, store and handle pharmaceutical products. Please confirm that this legal requirement must be observed.

Answer 9.6 - Positive.

Question 9.7 - Form 4 – conditions of employment in compliance with Maltese laws and ETC requirements– please confirm whether these have to be fully and completely adhered to irrespective of whether the concession contractor is foreign or local.

Answer 9.7 - Positive for any contracted employee working in Malta. Moreover, the Client reserves the right to seek confirmation of proper application of employment laws from the respective authorities.

Question 9.8 - Please confirm that where requirements refer to European clients/experience etc, this can be extended to include USA, Canada, Australia, Japan, Asia and EEA countries.

Answer 9.8 – Positive. At least two references are required, one of which must be from a European client which includes clients based within the European Union and the EEA.

Question 9.9 - Can one refer to the capabilities of its equipment suppliers to obtain the necessary points required, even if these suppliers are not part of the joint venture?

Answer 9.9 - No.

Email 10

Question 10.1 - It is understood that a WDL licence is required to operate as the contractor, may the contractor operate without such WDL licence and other permits from the MALTA Medicine authorities? If in the negative and such are mandatorily required, may the details of such JV party offering such abilities be added at a later such?

Answer 10.1 - NO the contractor or Joint Venture must operate within the local Maltese legislation in terms of WDL licence and must be authorised by the Medicines Authority. No the details of such JV offering such abilities must be included in the submission of the PQQ.