



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/412192/2013

Questions and answers relating to open tender procedure – EMA/2013/23/FI – High level business consultancy services

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Questions and answers

No.	Question	Answer
1	Must tenderers carry out all 10 listed consulting services (p.p. 9-11 of Technical Specification) to qualify for consideration, or would a sub-set be acceptable?	Tenderers must carry out all 10 listed consulting services. A sub-set is not acceptable.
2	Please can you clarify any differing information required in the response for Question 2.1 and Question 2.3? <i>"Question 2.1: What project management tools do you use? Describe your methodology for the execution of a project including the key deliverables and decision making process."</i> <i>"Question 2.3: Please describe how you propose to follow up the execution of a specific contract from signature until its end."</i>	A response to question 2.1 would need to include details of project management tools used (including IT tools) by the tenderer. It would also need to explain how these tools support the methodology the tenderer uses, i.e. how the tools assist with executing a project to achieve deliverables and how it takes into account the Agency's decision making process. A response to question 2.3 does not require any details regarding IT tools. It would need to include details of how the tenderer monitors and controls the progress of the project(s) as described in a particular specific contract. The specific contract (sample template included in Annex IV) also includes the budget for the project(s) and administrative formalities such as invoicing.
3	In relation to Question 3.2 – please can you clarify whether the information we provide should relate to the process of establishing managed/shared services with the intent of moving to that model for an area of the EMA operation at some point in the future, or to establishing managed/shared services with the intention of selling an EMA service to other stakeholders in the market, or to both. <i>"Question 3.2: Please describe your approach to establish managed/shared services in a public organisation."</i>	The information required is in relation to internal EMA operation. There is no requirement in relation to other parties.

No.	Question	Answer
4	Has the Agency let a similar contract for consultancy services previously?	No.
5	Who audits the accounts of the Agency?	The European Court of Auditors.
6	What are the key drivers that result in an anticipated 15,000 man days of consultancy work over the next four years?	Please see section 4 of the technical specifications (first paragraph).
7	In the tender specification document you provide an overview of the 10 areas where you require consulting services (section 4 – ‘subject of the tender’). Can you provide a rough indication of the volume of work to be expected across each of these 10 services?	It is not possible at this stage for the Agency to divide the volume across the different services.
8	In the tender specification document you provide an overview of the 10 areas where you require consulting services (section 4 – ‘subject of the tender’). The questions in Annex VIII do not specifically refer to these services. How should suppliers demonstrate their capability for each of the consulting services?	Capability to perform all the services covered by this tender is part of the selection criteria (see section 15: selection criteria: legal status and technical and professional capacity).
9	Is the Agency currently working with one or more consultancy providers in any of the 10 areas identified in section 4 – ‘subject of the tender’?	Yes, the Agency is currently employing some freelance staff for specific tasks in some of the 10 areas but not under a general framework contract as comprehensive as the one at stake.
10	Please describe what is meant by ‘intra-muros’ and ‘extra-muros’ in the context of this framework contract.	‘Intra muros’ means providing services on the Agency’s premises and ‘extra muros’ means providing services outside the Agency’s premises.
11	You anticipate a total volume of 15,000 man days over the four-year framework contract period. How will this volume of work be distributed between the three suppliers that win a place on the framework contract?	Please see section 12 of the technical specifications. The framework contracts are to be awarded in order of priority (first, second and third). This means that all requests for service would go initially to the first priority contractor. If the first priority contractor is unable to fulfil the requirements of an order within the requisite timelines or provides an

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		unsatisfactory service, the Agency may go to the second priority contractor and then to the third until the order is fulfilled.
12	Section 4 sets out 10 areas of consulting services in the scope of the framework agreement. However, most of the questions in Annex VIII (2.6 and 3.2 being exceptions) appear to mainly relate to general project, resource and quality management rather than these consulting services. How should tenderers provide evidence of experience of the services in scope?	Experience to perform all the services covered by this tender is part of the selection criteria (see section 15: selection criteria: legal status and technical and professional capacity).
13	Section 10.1 – you request prices in Euros, however the majority of the work will be UK-based. Why would you expect services to be priced in Euros rather than GBP?	The Agency holds its budget in Euros.
14	Section 15.2 requests a statement of average annual manpower and the number of staff of the tenderer who are able to fulfil the requirements of this tender in the last three years: - what form should this statement take? - how will this information be used in the selection process?	A simple statement with the requested information is required. There is no set format. This information will be used to assess the technical and professional capacity of tenderers and to ensure that they have sufficient manpower to perform all the services covered by this tender as indicated in section 15.
15	Section 15.3 requests completion of the Project Reference form. How many references are required? How will this information be used in the selection process?	There is no stipulated number of references because a tenderer might have one project which covers several different fields for example. The tenderer must provide a list of principal services provided in the last three years for similar contracts. This information is required to assess the technical and professional capacity of tenderers and to ensure that they have relevant previous experience in the provision of services in the fields covered by tenderer.

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16	Section 15.4 asks for a description of quality procedures. How will this information be used in selection?	The Agency requires a description of quality procedures for delivery of services relevant to this tender confirming adherence to ISO9000 or its equivalent and a copy of the certificate. This information is required to assess the technical and professional capacity of tenderers.
17	Section 16 indicates that each question will be scored out of 50 points, with 30 being the minimum standard. On what basis will scores be awarded? Is there any guidance as to the length of response expected?	Scores will be awarded according to the quality of the replies. Generic replies would not be expected to score highly. There is no minimum or maximum length of response.
18	How will the Agency score sector knowledge and experience?	Please see section 15 of the technical specifications: selection criteria: legal status and technical and professional capacity. The criteria for the contract are clearly stated here and include manpower with suitable qualifications and experience and relevant previous experience of the tenderer in the provision of services in the fields covered by this tender. Please note that responses to selection criteria shall not be scored by the Agency's evaluation committee. They shall be assessed on a pass/fail basis.
19	Section 12 'contractual details' includes the following paragraph...'it is the Agency's intention to sign multiple cascading framework contracts with a maximum of three suppliers ranked in priority order. If the first priority contractor is unable to fulfil the requirements of an order within the requisite timelines or provides an unsatisfactory service, the Agency may go to the second priority contractor in such a cascade and then to the third until the	The first priority contractor remains the same.

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	order is fulfilled'. Will the first priority contractor remain the same at all times, or does it change relevant to the nature of the work to be addressed?	
20	Does the Agency envisage any TUPE implications in establishing these services?	No
21	Is the Agency amenable to a clarification of contract terms (for example contract jurisdiction, IPR background/foreground, bidirectional confidentiality, liability limitation)?	As indicated in point 7 of the invitation to tender letter submission of a tender automatically implies acceptance of all the terms and conditions stipulated in the invitation to tender, the current technical specifications and annexes including the draft contract. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of the tender response. No negotiations shall be entered into on the draft contract terms. Should a tenderer require a clarification, this can be made but this shall not lead to any alteration of the draft contract.
22	Is the Agency amenable to a clarification meeting with your stakeholders?	No meetings may take place between the Agency and tenderers prior to submission of a tender. Contacts between the Agency and tenderers are strictly limited to questions submitted in writing, as set out in point 8 of the invitation to tender letter.
23	Would the Agency be amenable to a telephone or face to face meeting to clarify the business consultancy needs and objectives of the Agency?	Please see answer to Q.22.
24	Can you extend the deadline of 17 October to enable tenderers to prepare responses?	The Agency cannot extend the deadline of 17 October 2013 as the Agency wishes to conclude the evaluation this year to enable contracts to be in place for early 2014.

No.	Question	Answer
25	Can the EMA estimate the proportion of work under the framework that will be contracted on a fixed price basis?	It is not possible at this stage for the Agency to divide the volume across the different type of specific contracts i.e. time & means, quoted time & means or fixed price basis.
26	Can client identity be anonymised in project citations submitted in Annex VII of the tender dossier?	Yes, this is acceptable.
27	Does question 2.1 of Annex VIII refer to specific project management software (e.g. Microsoft Project) or to project management techniques or to both?	Please see answer to Q.2
28	Does the 10% cap on expenses relate to expenses incurred by each individual resource or to expenses across a project as a whole?	Taken into account the nature of the required services, hiring high level consultancy service, only expenses incurred by individual resource shall be charged. All other charged should be included in the consultancy rate.
29	Point 15 of the Tender Specification requires two Curricula Vitae for each of the personnel profiles listed in Section 4.4. Can the tenderer provide more than this number of CVs for each personnel profile?	No
30	In section 4 (Subject of the Tender), The Agency lists the domains where the high level consultancy services are required and discusses them in some detail as forming (or otherwise) the scope of the consultancy services framework. These are: • Strategy Development and performance management • Operational excellence and performance improvement • Business programme and project management • Business and technology alignment • Change management • Quality management • Human capital development	Please see answer to Q.12 and Q.18

No.	Question	Answer
	• Stakeholder communication • Corporate finance • Information management However, Annex VIII 'Award Criteria Questionnaire' comprise questions that are only specific to: 1. Planning and methodology 2. Delivery of services 3. Management of services The criteria in totality only appear to focus on eliciting the business programme, project management, and service delivery and management capabilities of the tendering entities. How will the Agency evaluate and mark responses from tendering entities that demonstrate their proven capabilities in delivering solutions and enabling transformation for their clients in the other domains as listed and discussed in Section 4?	
31	In relation to section 15 in the "Technical Specifications" (document ref.: EMA/552750/2013, WC500148956), point 4 under "Evidence required" (page 24) – is there a requirement for a formal Quality Assurance certification such as ISO9000 or equivalent, and is the provision of a copy of the relevant certificate mandatory, or would the Agency accept a description of the tenderer's Quality Assurance processes, provided that they are equivalent to the requirements to obtain a formal Quality Assurance certification?	Yes, this is acceptable.
32	In reference to Annex VII "Project Reference Form", please could you clarify what is expected to be indicated next to the Heading "Project Type" – as opposed to "Area(s) covered by the project"?	Project Type refers e.g. Time and Means, Quoted Time and Means or Fixed Price Project. Area(s) covered refers to the 10 listed consulting services (p.p. 9-11 of the technical specifications)
33	We would like to clarify the scope of technical specifications you would like us to describe in the proposal. The proposal specifies two different lists: - The four-coloured circular diagram/ framework provided on page 8	The four-coloured diagram summarizes the expected services where the table enters more into details.

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	- The table of 10 areas of services provided on pages 9-11. We assume that we should we address the combined spectrum of possible needs for consultant services (both from diagram and text) in our application. Please let us know if that is correct or if we should be focusing on one of the two primarily.	
34	In question 2.10 [in Annex VIII - Award criteria questionnaire] asks "Can you describe how you would help approach the business requirements gathering activities including how you would limit the complexity and support a cross Agency and horizontal approach?". Could you please confirm: a. Whether by "business requirements gathering activities" you are referring to how we would collect data and/ or perspectives from different stakeholders within and outside the Agency? b. Whether by "cross Agency and horizontal approach" you are referring to an approach to ensure all Agency departments are aligned on the required objectives and deliverables?	Yes, this is correct. Yes, this is correct.
35	We understand that any future invoices will be in Euros. Can you please confirm the billing country, as this is useful for our internal management of this response. For example, any future invoices may be paid out of London, in Euros, or Brussels.	All EMA payments are processed from our UK bank accounts independently of the billing country.
36	In the Guidebook for Tenderers (EMA/91282/2010) it is asked that all CVs do not indicate names but numbers that refer to a list with the actual names. The CV templates ask for other information such as date of birth, sex, nationality, and a picture. Should these information stay in the CVs or also be shifted to the separate list as well?	The only requirement is that the anonymity is respected i.e. do not include names; however the rest of the provided information may remain.
37	Please could the Agency further define "Advisory in VAT regulation" in the Technical Specification (requirements section 9), please?	The Agency is an EU Agency with protocols & privileges and therefore exempted directly or indirectly (recovering of funds) of VAT. However, the Agency could require high level advice on the implementation of (new) VAT regulation and other taxation

No.	Question	Answer
		matters in the frame of general advice on finance functions organisation, streamlining and improvement of business and financial processes within SAP environment.
38	When reading question 3.2 of the award criteria and the clarification to Question 3, we still see two possible interpretations regarding the managed/shared services question: • Interpretation 1: EMA would like tenderers to present their approach to consolidate a selection of EMA's internal processes in a shared service centre. This could for example relate to the creation of a shared service centre at EMA level that would centralize support processes in the area of finance, procurement and other "corporate" services such as meeting organization, logistics, etc. We have seen similar solutions being implemented in agencies similar to EMA (e.g. the creation of the Corporate Services unit in EFSA). We understand from the clarification that EMA is not looking for approaches to set up shared services together with e.g. agencies with a similar remit. • Interpretation 2: EMA would like tenderers to present their approach to manage the service delivery under the Framework Contract at corporate level (that is, the management of the framework contract). We know from experience that a Framework Contract covering a variety of different services can generate a number of service requests coming from different units. It is important that these requests are managed in a coordinated manner that is consistent with the overall objectives of the Framework Contract at the corporate level. A structured approach is therefore required to ensure a shared management of the services.	In this question the Agency is looking to establish the tenderer's general approach to managed or shared services. At this stage the Agency has no concrete plan to adopt such approach but would like to know how tenderers would handle it if needed. Yes, your understanding is correct. There are no plans to set up shared service together with other Agencies. The Agency will nominate its own co-ordinator/contract manager to manage the service delivery together with winning tenderer.
39	As a further clarification to your response to Question 10, please could you confirm;	a) Yes – please note that the Agency does not have any premises outside the UK however.

No.	Question	Answer
	a) Intra Muros work means work conducted at ALL agency premises including premises outside of the UK. Expenses are chargeable for this work in accordance with the agencies policy b) Extra Muros work means work conducted outside of the agencies premises (i.e. at the contractors own offices). Expenses are not chargeable for this work. c) Intra Muros also includes work where the contractor is required to conduct business on behalf of the agency (for example, visit one of the agencies stakeholders or suppliers). Expenses are chargeable for this work in accordance with the agencies policy	b) Yes c) Yes
40	As a further clarification to your response to Question 3 in the Q&A document, could you confirm; In our response to Award Criteria question 3.1 we understand that you are asking for us to demonstrate our ability and approach to help the EMA establish a shared service/managed service for its own internal business operations, rather than a shared service/managed service for consultancy services to be provided to the EMA?	The Agency is not presently looking into establishing shared service/managed service for its own internal business operations. Please see question 38 for further details.
41	Beyond the opening of tenders on the 23rd October, please could you illustrate your estimated timescales for evaluation, presentations/feedback and award? If presentations are required, what are the likely range of dates?	No presentations will take place as part of this tender. The evaluation committee expects to start work immediately upon opening of the tenders with a view to finalisation of the tender before the end of 2013.
42	In section 4.4 of the Technical specifications document you provide a table	All candidates proposed must have the minimum years of

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	detailing the 'Minimum years of consulting/business experience' required for each consulting grade profile. You cite "Bachelor and equivalent experience or Master's Degree" as a requirement for each grade up to Senior Manager. Please can you clarify whether a Bachelor degree is mandatory for each profile or whether equivalent experience (such as practical experience in the work environment) is acceptable as an alternative to formal university qualifications.	consulting/business experience indicated in the second column of the table in section 4.4 of the technical specifications. In addition all candidates must have technical qualifications, as indicated in the third column of that same table, namely either a Bachelor's or a Master's Degree. Please note that experience is not an alternative to the qualification.