



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers relating to Call for Expressions of Interest – ref. EMA/2012/08/CN

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Questions and answers

No.	Question	Answer
1	We are on the shortlist EMEA/2009/62/PHP and are interested to stay on the shortlist. Are we supposed to complete the application form and provide a new proof C relating to exclusion criteria?	The Call for Expressions of Interest EMA/2012/08/CN is a different and independent procedure from the one launched in 2009. The shortlist arising from this procedure expires in July 2012. Applicants wishing to remain on the shortlist are requested to complete the new application form and submit the full set of requested documentation. Regarding exclusion criteria, the requirement to provide proof may be waived only where such proof has already been submitted to the Agency for the purpose of another procurement procedure, and provided that the issuing date of such documents does not exceed one year and that they are still valid.
2	The application requests that we provide our most recent audited accounts (past 3 years). However, we do not intend to audit our accounts – are unaudited accounts sufficient for this purpose?	The call states: “If the applicant is not obliged to publish its accounts under the law of the State in which it is established, please supply copies of such accounting information as the applicant is willing to provide relating to the last three financial years or any period since the end of the last financial year, or a signed declaration regarding the applicant’s financial situation.”
3	I am trying to find further information on the closing date and submission documents.	The link to the call notice and relevant application form have been published on the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000320.jsp&mid=WC0b01ac05800a3991 The list of potential contractors will be valid until 2 April 2015. Applications to appear on this list may be submitted at any time during the period of validity of this list, with the exception of the last 3 months of that period (i.e. last possible date for submission is

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		2 January 2015).
4	I understand that you require proof of our company cash flow position. Unfortunately, we do not complete a regular cash flow analysis, so I would like to know exactly what information you require as proof of our cash flow position.	See response no. 2
5	We understand that we need to complete the application form and make a declaration upon honour (conflict of interest – Annex 2). We provide services for most pharmaceutical and medical device companies and public institutions involved in health care in France and in Europe and would like to have precision on what we have to declare as conflicts of interest. Should we provide you with a list of all our customers during the last years?	Annex II refers to conflicts of interest of the applicant to the Call and has to be completed in the applicant's name and signed by a duly authorised representative of the applicant. With this declaration the Applicant confirms that he shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of a future contract. Such conflicts of interest could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. It is recommended to include a list of customers in support of the application as part of the 'proof of technical and professional capacity'.
6	We intend to submit excerpts from German registers relating to the applicant. Is a certified translation of these excerpts required?	Applicants are not required to submit certified English translations of supporting documents, i.e. documents in any of the official languages of the European Union will be accepted.
7	Can you provide us with a model document for a sworn statement relating to Annex I Declaration upon Honour.	The proof required relating to exclusion criteria varies from country to country according to what is issued by that country's authorities. Advice is available on the European Commission's website (DG Internal Market) on proof which is acceptable for a number of countries: http://ec.europa.eu/internal_market/publicprocurement/2004_18/index_en.htm

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		The acceptable proof for legal and natural persons and public entities from the United Kingdom is a declaration on oath from a public notary or commissioner for oaths. An example for a sworn statement in front of a public notary or commissioner of oaths can be found on page 5 of the document "Frequently asked questions on exclusion criteria for public procurement procedures". This document may be downloaded from the Agency's website at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/09/WC500096857.pdf
8	Should the requested documentation supporting the "proof of technical and professional capacity" relate to the Principal Investigator who will conduct the studies?	The proof of technical and professional capacity may refer to the principal investigator and/or a number of responsible investigators that fulfil the requirements as per item 7.2 of the call for expressions of interest.
9	Annex 1, page 5 of the application form states that supporting documents provided must relate to, where considered necessary by the Agency, to company directors. In which cases is this necessary?	In principle, the supporting documents need to refer to legal or natural persons. Depending on the national legislation of the country in which the applicant is established, these documents must relate to entities with legal personality and/or natural persons; in the latter case, they must relate to the person(s) empowered to represent the applicant.

Document history

Version	Who	When	What
0.1	DV	08/05/2012	1-5
0.2	DV	25/05/2012	6-9
0.3			
0.4			
0.5			