



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 October 2018
EMA/718038/2018
European Medicines Agency
Legal Department

Ex ante publicity of a negotiated procedure

EMA/2018/42/LD – Advisory and support services in relation to EU data protection matters

The European Medicines Agency (hereinafter referred to as “the Agency” or “EMA”) intends to procure advisory services in relation to EU data protection matters - EMA/2018/42/LD.

The scope of this contract shall be:

the provision of advisory and support services in relation to EU data protection matters.

A negotiated tender with a maximum indicative budget of EUR 140,000.00 (exclusive of VAT) is planned to be launched in November 2018 and the contract awarded will be for twelve months.

Interested economic operators meeting the minimum technical requirements and the criteria below may express their interest by sending an e-mail indicating the reference number and subject of the procurement to AF-LD-TENDERS@ema.europa.eu together with the name, address and business details before 8 November 2018 at 1200H UK time.

The following minimum technical requirements shall apply to this framework contract:

- Compliance with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU;
- The working language of the Agency is English and the contractor must confirm that it will be able to communicate with the Agency in English for seamless implementation and execution of all the services covered within the scope of the contract, including responsibilities resulting from regulatory requirements such as Health and Safety and Data Protection, as well as for the efficient and timely response in respect to contract management; and
- Processing of personal data in connection with this service must comply with EU data protection legislation and in particular, Regulation (EU) 2016/679, the General Data Protection Regulation.

Interested economic operators should comply, at least, with the following criteria:

- All tenderers must have authorisation to perform the contract under national law.



- The average annual turnover of the tenderer must be a minimum value of EUR 280,000.00 for each of the last two financial years.
- Proven experience in providing advisory and support services in the field of data protection in the European Union of at least eight years. This shall include experience in conducting investigations or audits analysing compliance of personal data processing with EU legislation and implementing rules, covering legal, technical and organisational measures. Relevant experience in assessing and documenting the impact of information and communication technologies (ICT) solutions on data protection (e.g. data protection impact assessment) shall also be required. In addition, the tenderer shall have proven experience to work in the field of data protection with an EU institution or body, a national data protection authority or a national public body within the EEA/EU.
- Relevant professional qualifications and experience of a minimum of two individuals to be assigned to the Agency under the contract with at least one person having eight years of experience in providing advice and support in relation to the field of data protection in the EU.
- The tenderer and the assigned individuals shall not have a conflict of interest, which could affect the performance of the services of the contract. It follows that the tenderer shall not be in any situation that could compromise the impartial and objective performance of the contract with regard to the possible rendition of legal advice. Compliance with the specific rules of conflict of interest regulating the legal profession, including professional ethics rules shall be observed.

This publication does not constitute any obligation on the part of the Agency to invite any economic operator having expressed its interest to tender. Only the candidates invited to tender by the Agency will be admissible. Registering interest to receive an invitation to tender in a negotiated procedure of this type does not create any legal right or legitimate expectation on the part of any economic operator.