13/08/2016
EMA/303267/2016

Technical specifications for service concession

Meeting and training organisation – ref. EMA/2016/43/RS

Table of contents

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Technical specifications for a service concession in the area of meeting and training organisation

Ref. No. EMA/2016/43/R

1. Title of the invitation

This document contains the technical specifications for the invitation for proposals for the delivery of a service concession in the area of meeting and training organisation, ref. EMA/2016/43/RS.

Executive summary and indicative timetable

Item	Summary
Authority	European Medicines Agency hereinafter referred to as “EMA” or “the Agency”.
Purpose	This call for submission of proposals aims to put into place a concession arrangement with an economic operator for the delivery of professional, large-scale face-to-face meeting and training programmes tailored towards specific learning objectives in a number of the Agency’s areas of activity. This concession does not include the organisation of e-learning courses.
Type of contract	One concession contract is expected to be signed. The contract will lay down the legal, technical and administrative provisions governing the relations between the Agency and the concessionaire during its period of validity.
Duration of concession contract	Four years with two possible extensions (4 + 2 + 1). Maximum possible duration: seven years.
Places of delivery	1. EMA premises at 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom (or such other premises occupied by the Agency) 2. Alternative sites in close proximity to the Agency’s premises 3. Other EEA countries
Volume (indicative)	The estimated annual concession volume is approx. 140 days of events and includes approx. 40 events (training, meetings, workshops), plus 7 Information Days, and additional ad hoc events, as required. These figures may vary over the period of validity of the concession contract.
Joint Offers	Offers from consortia are permitted.
Launch in OJEU	13/08/2016
Closing date for receipt of proposals	30/09/2016 Please see the *Invitation to apply for a service concession* for detailed delivery instructions.
Completion of evaluation of	November 2016 (estimated)

Item	Summary
proposals	
Start of services	January 2017 (estimated)

2. Purpose and context of the invitation

The European Medicines Agency ("the Agency" or "EMA") is a decentralised agency of the European Union (EU) currently based in Canary Wharf in the Docklands area of London (E14). It began operating in 1995.

EMA's mission is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

EMA:

- Supports medicines development by giving scientific advice and providing guidance to developers of medicines;
- carries out robust scientific evaluations of medicines for human and veterinary use that are the basis of the European Commission's decision on whether a medicine can be authorised for marketing throughout the EU;
- monitors the safety of medicines in the EU throughout their lifespan; and
- provides information on medicines to healthcare professionals and patients.

EMA is responsible for the centralised procedure for the authorisation of medicines resulting in a single evaluation and a single authorisation for the whole of the EU. The centralised procedure is compulsory for certain medicines, including human medicines intended for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative diseases, designated orphan medicines intended for the treatment of rare diseases, and medicines derived from derived from genes, cells, tissue-engineering and biotechnology processes.

EMA coordinates the work of around 4,500 experts made available by the EU Member States. These experts evaluate the medicines and are members of the Agency's scientific committees, its working parties and groups.

The Agency's recommendations on medicines are based on rigorous scientific standards and the available evidence. Pharmaceutical companies applying for a marketing authorisation for a medicine have to submit comprehensive data on the quality, safety, and efficacy of their medicine. These data are scrutinised by the Agency's experts, who will recommend the marketing authorisation of a medicine if the data convincingly show that its benefits outweigh its risks.

EMA is a scientific body. Decisions on whether to grant, suspend or revoke a marketing authorisation for centrally authorised medicines are issued by the European Commission, based on the Agency's scientific opinions. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU and EEA-EFTA states (Iceland, Liechtenstein and Norway). This allows the marketing authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EEA.

To fulfil its tasks, the Agency works closely with its partners and stakeholders. These include national competent authorities for human and veterinary medicines, patients and consumers and their organisations, healthcare professionals, the pharmaceutical industry, academia, and international regulatory bodies. The level of interaction with the various groups is based on the principles laid down in the EMA Stakeholder Relations Management Framework. Transparency and effective communication require open, proactive and meaningful dialogue and an important means of achieving this is through the organisation of large-scale face-to-face training and meeting events.

3. Subject of the concession

3.1. Scope

The Agency considers entering into a concession contract for the delivery of professional, large-scale face-to-face training and meeting programmes tailored towards specific learning objectives covering a number of its areas of activity.

The successful applicant will act as the conference organiser for the Agency in the delivery of these educational offerings (training courses, information days, workshops, meetings).

The exact frequency of the training courses and other events will be determined by the Agency, depending on the stakeholders' interest in the courses offered.

Subject to availability, the events will mostly take place at the Agency's premises in Canary Wharf, London (or such other premises occupied by the Agency from time to time). The provisions of section 3.8. shall apply to the use of the Agency's premises for such events.

If meeting room facilities are not available at the Agency's premises, it will be the concessionaire's responsibility to secure and pay for an alternative site, preferably in close proximity to the Agency.

There will be instances where training courses will also be organised in collaboration with national competent authorities in one of the countries of the EEA. In such instances it will be the responsibility of the concessionaire to liaise directly with the EU Network Training Centre (EU NTC)[1], and to secure and pay the necessary meeting room facilities.

3.2. Rationale

The rationale for the service concession with regard to the scope outlined above is the delivery of professional, large-scale training and meeting programmes for the Agency tailored towards specific learning objectives covering a number of its areas of activity.

The delivery of these wide-ranging, highly customised and extensive programmes is absolutely essential to reach all stakeholders that have reporting and other obligations towards the Agency and national competent authorities in the EEA. The concessionaire will be instrumental in achieving these objectives from an administrative point of view, taking into account the high volume of stakeholder interaction required.

[1] The EU Network Training Centre is a joint EMA/HMA (Heads of Medicines Agencies) initiative to harmonise training in Europe through a common online platform for scientific and regulatory training - http://www.hma.eu/otsg.html

3.3. Minimum requirements to be met by the applicant

The following minimum requirements must be met by the applicant for it to be considered compliant with the technical specifications. Applicants must provide a completed declaration which can be found in **Annex IV**. Failure to confirm compliance with all the following requirements shall result in elimination from the concession procedure:

- 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.
- A dedicated contact point for pre and post training support must be provided.
- Acknowledgements of registration for training courses and information days must be dispatched within 24 hours.
- The registration portal must be updated on a daily basis with the number of available spaces. Once all available spaces have been filled, a waiting list on a first-come, first-served basis must be created.
- Instructors must have a minimum of two years' experience in their chosen area of expertise.
- The material used in training courses and information days provided by the concessionaire must be printed double sided and printed on FSC paper, avoiding the use of plastic folders.

3.4. Event objectives

The exact objectives for each event will be defined by the Agency as necessary at the time of the programme development. As applicable, the Agency will also determine the composition of the relevant programme committee, the composition of which will be determined by the subject matter, but will typically include at least one EMA staff member plus other experts. Initial guidance as regards event objectives is provided under point 8. 'Estimated concession volume'.

3.5. Target audience

The target audience of the Agency's training and meeting programmes includes its external stakeholders, representing patient and healthcare professionals, academia and industry as well as other interested parties. The table in Appendix B provides the key stakeholders targeted for each proposed event.

3.6. General terms and conditions

The Agency shall approve content definition and all content created by the concessionaire.

Publication of all communication and promotional material in the context of the activities outlined in section 3.1. will require specific approval of the Agency.

Ownership of copyright of all materials developed within the framework of the activities specified in section 3.1. remains with the Agency. Additional information regarding the ownership of copyrights may be found in Article II.5 of the draft concession contract.

The organisation of a course will require a minimum of 10 participants. In cases where there are less than 10 interested participants the course shall be cancelled and re-scheduled at a future date in

agreement with the Agency. Registration fees shall be refunded by the concessionaire to the participants who have already paid. Any other expenses arising from the cancellation (e.g. room hire costs etc.) shall be borne by the concessionaire.

English will be the official language for all training courses and meetings and associated materials. Where training is organised locally in an EEA country, it may be necessary for the concessionaire to provide a trainer with local language skills, although training material will be provided in English only.

Events shall be recorded and the recordings subsequently be made available either to the general public via the Agency's website, and/or for training purposes to staff at the European Medicines Agency and at National Competent Authorities in EEA countries via the EU Network Training Centre[2]. The need for recording and extent of dissemination will depend on the content and shall be agreed with the Agency on a case-by-case basis. It will be the responsibility of the concessionaire to obtain the necessary permissions from participants.

The recording of events taking place at the Agency's premises will be the responsibility of the EMA Audiovisual Team. The concessionaire shall be responsible for the recording of all events taking place outside the Agency (the relevant technical specifications will be provided as required).

3.7. Pricing strategy

The pricing model shall be based on the following general principles:

- **Waiver of fees:**

  a) Training courses:

  - for up to five attendees from the European Medicines Agency (excluding speakers)
  - for one participant per national competent authority in EEA countries and from national competent authorities that are part of the EU enlargement programme (up to a maximum of five per module)

  b) Information days and other events:

  - for up to ten attendees from the European Medicines Agency
  - for one participant per national competent authority in EEA countries and from national competent authorities that are part of the EU enlargement programme (up to a maximum of ten per module)

  Registrants from the European Medicines Agency and national competent authorities shall not have the right for first refusal. All registrations shall be treated on a first-come, first-served basis.

- **Price reductions:**

	Description	Discount
A	For additional participants from national competent authorities in the EEA, non-commercial organisations[3] and universities[4]	50%[5]

[2] The EU Network Training Centre is a joint EMA/HMA (Heads of Medicines Agencies) initiative to harmonise training in Europe through implementing a common online platform for scientific and regulatory training.
[3] 'Non-commercial' organisations include not-for-profit organisations like patient organisations, charities etc.
[4] 'University' refers to full-time staff and full-time students
[5] Proof of affiliation will be at the discretion of the concessionaire.

	Description	Discount
B	For participants from SMEs	35%[6]
C	For participants who register for more than one course ('multiple course discount')	20%

- **Other considerations:**
  - The concessionaire will cover travel and accommodation expenses and a daily allowance or honorarium for instructors/speakers (see also section 3.9.2.).
  - Participants from SMEs (micro-, small- and medium-sized enterprises) will need to send proof of their SME status to the training/meeting organiser along with their registration form.
  - The concessionaire may, in agreement with the Agency, limit the number of attendees with discounted fees per meeting in order to cover its meetings costs.
  - Prices for training modules that may be developed during the validity of the concession contract and that are not listed under Section 8. 'Estimated concession volume', shall be subject to agreement with the Agency.
  - The concessionaire will pay for meeting room facilities, refreshments and lunches.
  - For pricing purposes relating to training courses and information days taking place at the EMA premises, it is suggested to include an allowance of £25.00 per person to cover for two coffee breaks, lunch, consumables and labour costs. Applicants should note that this estimate is indicative only and prices are subject to change during the duration of the concession contract.

3.8. Support from the European Medicines Agency

The Agency will contribute, on the basis of its coordination role and as specified in this section, to the preparation of the events as outlined in section 3.1.

For each event topic the Agency shall appoint a coordinator responsible for the development, implementation and coordination of the training or meeting and who shall act as the primary contact point for the concessionaire.

Depending on availability, the Agency will assist in securing meeting rooms at its premises for events taking place at the Agency. The concessionaire will be encouraged to block EMA meeting rooms as soon as possible and as soon as the events schedule has been agreed with the Agency. It should be noted that EMA Committee meetings will take precedence and rooms will be blocked well in advance for that purpose. The Committee meeting dates (up to 2018) can be found in the event and meeting calendar published on the EMA website (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/events_and_meetings_calendar.jsp&mid=WC0b01ac058004d5c3).

[6] For the purpose of the training concession, the fee reduction applies to those SMEs that are included in the Agency's SME register only. The EMA SME Register may be consulted via this link: https://fmapps.emea.europa.eu/SME/index.php

In principle, the Agency will respect its agreement when meeting rooms have been allocated for externally organised events. However, these allocations cannot be guaranteed in case of unforeseen events. In such situations the Agency will give as much advance notice as possible and inform the concessionaire as soon as the need for a cancellation becomes apparent.

The Agency has in place a policy on the recuperation of costs incurred when hosting external organisations' events at its premises. This policy (see **Appendix A**) foresees that the external organisation shall be charged a cost per paying participant in the event. The concessionaire shall pay the Agency for use of the Agency's premises in accordance with the policy set out at **Appendix A** (or such other policy as notified by the Agency to the concessionaire from time to time). Guidance on the payment procedure is provided in the document 'Instruction paper for external organisations', as attached to **Appendix A**. Whilst the Agency does not charge VAT on the venue rate per delegate, catering expenses will be subject to VAT.

The recording of events taking place at the Agency's premises will be the responsibility of the EMA Audiovisual Team.

3.9. Roles and responsibilities of the concessionaire

The following provides an overview of the roles and responsibilities of the concessionaire. Detailed roles and responsibilities will vary from event to event and shall be agreed on a case-by-case basis and in advance with the responsible Agency coordinator.

3.9.1. Material and technical support

The concessionaire shall:

- Work with the Agency to develop an annual events plan.
- Support the Agency in preparing and developing course programmes and content. The concessionaire is expected to deliver a first draft of programmes for input by the Agency (see also section 3.9.7.). The Agency approves content definition and all content created.
- Work with the Agency to develop and update the training material.
- Assist in the drafting and proofreading of new or modified training materials. It is anticipated that all materials shall be reviewed and approved by the Agency prior to the organisation of each training.
- Be responsible for the printing and distribution/provision of the training material.
- Collect attendee and instructor feedback and provide the originals of such feedback to the Agency after each training course.
- Offer follow-up training for participants in the form of webinars.
- Supply instructors with a CD (or other electronic media) including updated training course material, whenever substantial updates have been implemented.
- Supply all participants with a CD (or other electronic media) of the training course material (password protected).
- Supply all past participants with a CD (or other electronic media) including updated training course material whenever significant updates have been implemented.

- Provide refreshments during breaks and lunches.
- Where applicable, identify and pay costs associated with hiring suitable venues for training other than the Agency.
- Provide meeting management services.

3.9.2. Instructors / Speakers

The concessionaire shall:

- Establish a pool of committed instructors approved by the Agency (professional instructors and volunteer instructors from national competent authorities, academia, public health or standardisation institutions, or other relevant stakeholders). CVs of all instructors are to be made available to the Agency in advance.
- Ensure and facilitate the availability of instructors for each course (and back-up instructors in case of non-availability).
- Include where possible volunteer instructors from national competent authorities or other stakeholder groups, and professional instructors for each course.
- Remunerate instructors/speakers as follows:

    a) Training:

    Instructors shall be paid/reimbursed travel and accommodation, in addition to which they may choose to receive a daily allowance for other expenses on production of original receipts, or receive an honorarium. Instructors/speakers from national competent authorities shall not be entitled to an honorarium.

    b) Information Days and other events:

    All speakers shall have their registration fee waived.

- Organise 'train-the-instructor' sessions at the premises of the Agency.
- Reimburse travel and accommodation costs for volunteer instructors from national competent authorities when they attend the 'train-the-instructor' session.
- Organise follow-up training for instructors if requested by the Agency.
- Prepare training standard operating procedures (SOPs) including aspects such as competency assessment.
- Prepare instructor competency evaluation forms subject to the approval of the Agency.
- Perform the competency assessment of training participants, as required.

3.9.3. Training in EEA countries

The concessionaire shall:

- Organise training in EEA countries as agreed with the Agency.
- Identify and pay costs associated with hiring suitable venues for training in EEA countries.
- Provide meeting management services.

- If requested, ensure that at least one instructor will have local language skills in support of the training to be conducted.

3.9.4. Conference services

The concessionaire shall:

- Recruit and register the participants and collect the fees.
- Provide relevant information to participants including travel and accommodation information.
- Provide participant lists to the Agency.
- Distribute, collect and summarise course and instructor evaluation forms and provide feedback (including copies of the evaluation forms) after each training course for improvement to instructors and to the Agency.
- Facilitate training of instructors and participants with regard to material and system updates (e.g. webinars).
- Provide certificates of attendance as appropriate and agreed in advance with the Agency.

3.9.5. Promotion

The concessionaire shall:

- Prepare promotional material in collaboration with the Agency.
- Provide all promotional material to the Agency within a reasonable timeframe (minimum 14 working days) for approval before publication and release.
- Provide all promotional activities associated with the programme including brochures for attendees, FAQs and electronic newsletters and a communication plan (e.g. rationale for the programme, value and benefits, who should participate, how to participate etc.).
- Ensure that the Agency logo is shown in all communication and information distributed relating to the event (note: the Agency logo must not be used by the concessionaire outside the scope of this concession contract).

3.9.6. Certification

The concessionaire shall maintain an electronic record of attendance and certified users accessible by the Agency.

3.9.6.1. Attendance certificates

The concessionaire shall issue attendance certificates to all participants in training courses and other events.

3.9.6.2. Competency assessments / User certificates

In relation to certain training courses, and subject to approval by the Agency, the concessionaire shall:

- Perform competency assessment on behalf of, and based on the criteria developed by, the Agency.

- Distribute and collect competency assessment forms (to be archived at the Agency).
- Communicate competency assessment results to participants.
- Provide user certificates to the participants.
- Provide post-training support.

3.9.7. Additional roles and responsibilities relating to the organisation of information days, workshops and other meetings

The concessionaire shall:

- Organise information days, workshops and other meetings as agreed at the Agency's premises or in locations in the EEA.
- Facilitate programme committee meetings and development of the programme content. Planning meetings shall be hosted by the Agency as necessary.
- Invite speakers from a list of suitable candidates supplied by the Agency.
- Provide templates for slide presentations.
- Produce official meeting material based on the documents provided by the Agency.
- Coordinate participants' materials and handouts.
- Implement revisions of the meeting material based on feedback from the participants, speakers and the European Medicines Agency.
- Provide all promotional activities associated with the programme, including brochures for attendees, FAQs and electronic newsletters, and a communication plan (e.g. rationale for the programme, value and benefits, who should participate, how to participate).

3.10. Reporting

The concessionaire shall collect attendee and instructor feedback and provide such feedback in summarised format (including copies of original feedback) to the Agency after each event.

At the end of each calendar year the concessionaire shall provide both a summary report and a financial report of all activities during the past twelve months, including statistics.

The concessionaire shall provide the Agency with an annual audit report of its financial statements relating to the services provided on behalf of the Agency. The audit is to be performed by an independent auditor. The first such audit shall be due within three (3) months following the first anniversary of the coming into force of the concession contract.

4. Participation

4.1. Agreements on public procurement

Participation in this concession procedure is open on equal terms to all natural and legal persons falling within the scope of the Treaties. This includes all legal entities registered in the EU and all natural persons having their domicile in the EU. Participation is also open to all natural and legal persons registered or having their domicile in a non-EU country which has an agreement with the European

Union in the field of public procurement on the conditions laid down in that agreement. The rules of access to the market do not apply to subcontractors.

The concession procedures of the Agency are not however open to applicants from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA").

4.2. Subcontracting

If the applicant envisages subcontracting any part of the concession, **Annex V** should be completed indicating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor. In case of *intra muros* services[7], the names, contacts and authorised representatives of subcontractors involved in the performance of the concession must also be stated.

Attached to the completed **Annex V** should be a signed letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the applicant if it is awarded the concession and the extent of the resources that it will put at the applicant's disposal for the performance of the concession.

A completed **Annex III** is required by each subcontractor where more than 10% of the concession shall be executed by subcontractors. Applicants should note their obligation to replace a subcontractor if it is in an exclusion situation or does not meet a specific selection criterion.

If such documents are not provided, the Agency shall assume that the applicant does not intend subcontracting.

5. Additional documentation available

- Further information about the work of the Agency can be obtained on its website: http://www.ema.europa.eu.
- The EMA Stakeholder Relations Management Framework is available on the EMA website: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/06/WC500208987.pdf
- Information on EMA's key partners and stakeholder groups can be found at:

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000212.jsp&mid=
- Information on micro-, small- and medium-sized enterprises (SME) can be found at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000059.jsp&mid=WC0b01ac05800240cc

6. Site visit

Not applicable.

7. Variants

Not applicable.

[7] Services provided on the Agency's premises.

8. Estimated concession volume

The subject of this concession is the organisation of face-to-face training courses and meetings.

The estimated annual requirements for the initial four years of the concession contract (2017 to 2020) are provided in **Appendix B**. In case the Agency opts to extend the concession contract further (see Section 10. 'Concession contract details'), the annual requirements for the remaining duration of the concession contract will be communicated to the concessionaire at least six months prior to the end of the current calendar year.

The individual event topics and training modules are provided as an indication only and, as such, are not binding. The estimated concession volume provided in **Appendix B** may vary over the period of validity of the concession and will be subject to annual revision. It shall be agreed annually in advance with the Agency, with the Agency reserving the right to change the number of offerings based on demand.

The exact frequency of training courses and other events will be determined by the Agency and discussed with the concessionaire depending on the stakeholders' interest in the events offered. The duration of individual events can be amended by the Agency taking into account initial experience and feedback from attendees. The Agency also reserves the right to amend the requirements for competency assessment for each of the courses.

As a general guidance, an estimation of attendance figures is provided below; these figures are indicative only and are not to be considered as binding:

- Information days: 100 to 130
- Hands-on training courses: 10 to 18
- Other training courses, workshops and meetings: 50 to 60
- Other training courses aimed at stakeholder group 1 (i.e. regulators) only: 18 to 20

9. Price

9.1. Pricing strategy

See section 3.7.

9.2. Currency of offer

Prices should be submitted in Euro. The costing sheet attached to these specifications must be used to submit a financial offer – **Annex II**.

Please note that the financial costing sheet in **Annex II** must be submitted in separate binders or folders, and on separate CD-ROM/DVD/USB memory stick which must be clearly labelled.

9.3. All-inclusive prices

Prices submitted in response to this concession invitation must be inclusive of all costs involved in the performance of the concession. No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

9.4. Price revision

Prices submitted in response to this concession invitation shall be fixed and not subject to revision during the first year of performance of the concession.

From the beginning of the second year of performance of the concession, prices may be revised upwards or downwards each year, where such revision is requested by one of the concession parties by notice served no later than three months before the anniversary of the date on which the concession contract became effective.

This revision shall be determined by the trend in the European Index of Consumer Prices (EICP)[8] published by the Statistical Office of the European Union in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (European Union index) - http://ec.europa.eu/eurostat.

Revision shall be calculated in accordance with the following formula:

$$Ar = Ao * \frac{Ir}{Io}$$

Where

Ar = revised total amount

Ao = total amount in the original offer

Io = index for the month in which the concession contract enters into force

Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices.

9.5. Costs involved in preparing and submitting an application

The Agency will not reimburse any costs incurred in the preparation and submission of an application. Any such costs must be paid by the applicant.

9.6. Period of validity of the application

Applicants must enclose a confirmation that the application (including prices) is valid for nine months from the closing date for receipt of applications.

9.7. Protocol on the Privileges and Immunities of the European Union

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Applicants must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

[8] The template has been set up for price revision for EUR contracts.

10. Concession contract details

A draft concession contract is attached to these Technical Specifications as **Annex VI.** Applicants must confirm acceptance of the draft concession contract and terms and conditions of the concession as part of their response as part of its declaration in **Annex I**.

The Agency wishes to conclude a concession contract for the delivery of professional, large-scale face-to-face training and meeting programmes tailored towards specific learning objectives covering a number of its areas of activity.

The concession contract shall be valid for an initial period of four years with the possibility of two renewals. The first renewal shall be for two years, and the second for one year (maximum possible duration is seven years).

11. Exclusion criteria

All applicants shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in this Annex. In case of subcontracting, applicants should note that there will be an obligation to replace a subcontractor if it is in an exclusion situation.

The successful applicant shall provide the documents mentioned as supporting evidence in **Annex III** before signature of the concession contract and within a deadline given by the Agency.

The Agency may waive the obligation of an applicant to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the applicant shall declare on its honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in its situation have occurred.

12. Selection criteria

12.1. Legal and regulatory capacity

12.1.1. Requirement:

All applicants must have authorisation to perform the concession under national law.

12.1.2. Evidence required:

All applicants shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their response, stating that they have the legal and regulatory capacity to pursue the professional activity needed for performing the concession to meet the requirement as stated in 12.1.1.

The applicant shall provide the following evidence listed below upon request by the Agency at any time during the concession procedure:

- Authorisation to perform the concession under national law, as evidenced by inclusion in a relevant professional or trade register (except for international organisations), membership of a specific professional organisation, express authorisation of entry in the VAT register.

12.2. Financial and economic capacity

12.2.1. Requirement:

- Applicants must be financially feasible and in a stable financial position and have the economic and financial capacity to perform the concession.
- In order to be financially feasible, an entity must be able to demonstrate a favourable total score for the following: liquidity, capability to cover its short-term commitments; solvency, capability to cover its medium and long-term commitments; and profitability, generating profits, or at least with self-financing capacity.

12.2.2. Evidence required:

All applicants shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their response, stating that they fulfil the applicable financial and economic criteria set out in 12.2.1.

If the applicant is a company and is otherwise required under the law of the State in which it is established to publish its accounts, it shall provide upon request by the Agency at any time during the procurement procedure, including from subcontractors if requested:

- financial statements or their extracts for the last two financial years for which accounts have been closed.

If, for some exceptional reason which the Agency considers justified, the applicant is unable to provide the documentation mentioned, it may prove its financial and economic capacity by any other means which the Agency considers appropriate.

If the applicant relies on the capacities of other entities (e.g. a parent company), a written undertaking on the part of those entities confirming that they will place the resources necessary for performance of the concession at the disposal of the applicant for the period of the concession contract may be requested by the Agency. In such case the Agency may require that the successful applicant(s) and such entities are jointly liable for the execution of the concession contract.

The Agency may waive the obligation of an applicant to submit the documentary evidence referred to above if such evidence has been submitted to it for the purposes of another procurement procedure and provided that the documents are up-to-date.

The following ratios will be calculated to evaluate financial feasibility:

Ratio	Formula	Scoring		
		0	1	2
Liquidity	*Liquidity* Current assets – Stocks – Debtors > 1 year / Short term debts	Below 50%	Between or equal 50% and 100%	Above or equal 100%

Ratio	Formula	Scoring		
		0	1	2
Solvency	*Financial independence* Own funds Total liabilities	Below 20%	Between or equal 20% and 40%	Above or equal 40%
	Debt ratio Own funds Medium- and long-term debts (MLT)	Below 30%	Between or equal 30% and 60%	Above or equal 60%
Profitability	*Coverage of deposits and borrowed funds by Self Financing Capacity (SFC*)* SFC Medium and long terms debt (MLT) * SFC = net result + amortisation	Below 25%	Between or equal 25% and 50%	Above or equal 50%
	Profitability Gross operating result Turnover	Below 5%	Between or equal 5% and 15%	Above or equal 15%

A score is awarded according to the calculated values of each of the five ratios and the maximum score an entity may obtain is a total of 10 points.

In order to meet the financial capacity criterion, the applicant must obtain a score of at least 4 points out of 10.

If it seems that the financial feasibility evaluation does not provide a favourable picture of an organisation's financial status, economic and financial capacity may be proven by any other means which the Agency considers appropriate.

In case of joint applications the financial and economic capacity shall be evaluated as a whole.

12.3. Technical and professional capacity

12.3.1. Requirements:

- Experience in delivering training courses and meeting organisation as described in the technical specifications.
- Measures established to ensure high quality and timely services to customers.
- Sufficient manpower involved in meeting and conference services (minimum three staff) and suitably qualified managerial staff with at least three years' experience in meeting and conference organisation, and access to a pool of qualified instructors with at least two years' experience in delivering training in a variety of areas.
- Measures established to reduce the environmental impact in the performance of the concession.

Applicants must meet all of the above requirements.

In case of joint offers and subcontracting these criteria shall be evaluated as a whole.

12.3.2. Evidence required:

All applicants shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their response, stating that they fulfil the applicable technical and professional criteria set out in 12.4.1.

Any applicant with a professional conflicting interest which prevents it from performing the concession adequately may be rejected on the basis of not fulfilling selection criteria for professional capacity.

The applicant shall provide the documents listed below upon request by the Agency at any time during the concession procedure:

(a) A list of the principal services in the field of training and meeting organisations provided in the past three years, with the sums, dates and clients, public or private accompanied upon request by statements issued by the clients;

(b) A description of measures employed to ensure quality of services (quality management for customer service; internal quality management standards);

(c) A statement of the average annual manpower and the number of managerial staff of the economic operator for the last three years; the educational and professional qualifications, skills, experience and expertise of the persons responsible for performance:

- Curricula Vitae for the managerial staff, in particular those of the persons responsible for providing the services;
- Curricula Vitae of 3 trainers without indication of names, clearly showing the qualifications and professional experience within the relevant area.

  Curricula Vitae should be submitted without indication of any name or date of birth. Each Curriculum Vitae should bear a number only and the proposal should include a separate list showing the association between these numbers and actual names.

  The Agency requests that Curricula Vitae are submitted using the Europass template: https://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions

(d) An indication of the environmental management measures that the economic operator will be able to apply when performing the concession.

12.4. Professional conflict of interest

The verification of professional conflict of interest under the selection criteria refers both to tenderers (including all consortium members) and subcontractors to be engaged in the provision of the service covered by the present procurement procedure.

The EMA may reject tenderers under the selection criteria for the technical and professional capacity in case of professional conflicting interest that may negatively affect the performance of the contract, as per Art. 148(6) RAP[9].

EMA is placed in a fiduciary capacity regarding the regulation of medicines within its remit and has policies and procedures in place to ensure it works independently, openly and transparently to uphold

[9] Article 148(6) RAP states: "A contracting authority may conclude that an economic operator does not possess the required professional capacity to perform the contract to an appropriate quality standard where the contracting authority has established that the economic operator has conflicting interests which may negatively affect its performance."

the highest standards for the evaluation and supervision of medicines. Management of conflicts of interests is pivotal to the Agency's accountability and governance for engagement with its stakeholders. Medicines developed by the pharmaceutical industry are subject to evaluation and monitoring by the EMA for compliance with EU regulatory requirements. Therefore, pharmaceutical industries are in conflict of interest with regard to the subject of this tender.

Professional conflicting interest will be assumed if:

- the tenderer and/or subcontractor is a pharmaceutical company. For the purpose of this tender, a pharmaceutical company is defined as any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. The definition includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might be carried out in house) are outsourced on a contract basis. This includes contract research organisations or consultancy companies providing advice or services relating to the above activities.

12.4.1. Evidence required:

The tenderer and/or the subcontractor shall sign a declaration of honour stating that it/they is/are not in one of the situations of professional conflict of interest mentioned above (see **Annex III**).

Moreover, the assessment of the above criteria will be carried out based on all the documents and information provided in the offer, in particular the evidence for the selection criteria. If necessary (e.g. in case of doubt), the EMA will ask for clarifications regarding the issue.

The tenderers shall note that if it is found that the tenderer itself, and/or one or more consortium member(s), and/or one or more subcontractor(s) are in conflict of interest, the offer will not be further evaluated and will be rejected.

The tenderers and/or the subcontractor are obliged to report to the contracting authority any change in their situation related to the absence of conflict of interest throughout the implementation of the contract.

13. Award criteria

In order to determine the most economically advantageous application, the award criteria which will apply to this concession procedure are as follows:

Qualitative award criteria:	60%
Price:	40%
Total	100%

For joint applications the award criteria shall be evaluated in relation to the application submitted as a whole, including all joint applicants and subcontractors.

13.1. Qualitative award criteria

The qualitative criteria which will apply to this concession procedure are set out in tabular format below including the available points and minimum scores. Any applicant not achieving the minimum scores indicated below will be eliminated and not evaluated for price. The qualitative award criteria shall account for **60% of the weighting** for this concession procedure.

No.	Qualitative award criterion	Weighting	Maximum points available	Minimum points, which must be achieved
A	**Management and reporting**	**20**	**300**	**180**
A.1	Management	10	150	90
A.2	Evaluation and reporting	10	150	90
B	**Instructors**	**20**	**400**	**240**
B.1	Availability and selection	10	200	120
B.2	Replacements and briefing	10	200	120
C	**Organisation & Cancellation Policy**	**20**	**300**	**180**
C.1	Approach	10	150	90
C.2	Promotion	10	150	90
	TOTAL	60%	1000	600

In order to evaluate the above qualitative award criteria, the following documents are required.

Applicants should provide responses on each of the technical criteria in separate documents (maximum two A4 pages per sub-criterion with the possibility of providing annexes where requested or considered essential in support of the response).

- Criterion A: Management and reporting
    - Detailed description of how the concession contract will be managed, including proposed interaction with the Agency.
    - Detailed description of the applicant's approach to evaluate, report and follow-up on training delivered. Sample reporting templates should be provided.
- Criterion B: Instructors
    - Detailed description of how the applicant will ensure the ongoing availability of a pool of qualified and experienced instructors.
    - Detailed description of policy on replacement of instructors and briefing of new instructors.
- Criterion C: Organisation & Cancellation policy
    - Detailed description of the applicant's approach to organising a typical event (including registration process, support on the day, attendance certificates, follow-up), including description of cancellation policy.

- Details of how the applicant will promote the various meeting offers, taking into consideration the different stakeholder groups that the events are aimed at; samples of proposed promotional material should be provided, if available.

13.2. Price

Only those applicants which have obtained the stipulated minimum score shall be evaluated for price and thus for award of the concession.

Price shall account for 40% of the weighting for this concession procedure.

The award criteria for price shall be evaluated according to the following formula:

$$\frac{\text{Lowest price x weighting for price}}{\text{Applicant's price}}$$

For the purposes of evaluation "price" in this formula shall be the 'Overall total cost' arising from the calculation based on the scenarios for evaluation of price provided in the costing sheet in **Annex II** calculated to two decimal places.

These scenarios are indicative only for the purposes of evaluation and are not binding on the Agency as a future purchase but uses prices which shall be those charged by the concessionaire if a concession contract is awarded.

The applicants' attention is drawn to Article 151 of the Rules of Application of Regulation (EU, Euratom) No. 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, as amended, concerning abnormally low tenders.

13.3. Total points for award criteria

Following evaluation of price, the points for the qualitative award criteria and the points for price shall be added together to arrive at a grand total to two decimal places.

14. Applications to be submitted

Applicants must submit the following:

Documents required
Letter enclosing the application on the official letter headed paper of the applicant and signed by an authorised representative of the applicant.
Application (excluding financial offer) in one original paper copy with one copy of all documents on CD-ROM, DVD or USB memory stick. To be submitted following the instructions on inner and outer envelopes in the invitation letter.
A completed concession information sheet and declaration on submission – **Annex I.**
A detailed financial offer using the costing sheet attached in **Annex II**, and exclusive of VAT, signed by an authorised representative of the applicant, clearly labelled and **submitted in paper copy in separate binders or folders and on separate CD-ROM, DVD or USB memory stick.**
A completed declaration relating to exclusion and selection criteria – **Annex III**.

Documents required
A completed minimum technical requirements declaration – **Annex IV.**
A completed subcontractors form if applicable– **Annex V.**
A completed checklist – **Annex VI**.
Documentation requested to enable assessment of Award Criteria (point 13.1. above).