



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers relating to service concession ‘Pharmacovigilance Training’ – reference number EMA/2014/35/RE

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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Questions and answers

No.	Question	Answer
1	Can we respond only to part of this tender i.e only for preparation of training courses and NOT for delivery of training and conference arrangements/logistics or do we need to do the entire thing?	The service concession ref. EMA/2014/35/RE relates to the delivery of training and meeting programmes in the area of pharmacovigilance. A partial response would not be acceptable. In this context attention is drawn to section 4.2. of the technical specifications relating to consortia and partnerships which may be formed to deliver the concession agreement.
2	Could you kindly let me know what is the approx. value of this contract?	The contract is quantified in terms of the volume of services and not by a financial value. Please see section 6 of the technical specifications ('Estimated concession volume').
3	We are a digital learning company and, whereas, we can't provide the F2F services you're looking for, we can do the elearning side. Is this available as a separate lot?	The service concession 'Pharmacovigilance Training' does not include a separate lot for e-learning. The subject of the concession is strictly the organisation of face-to-face training and information days.
4	Could you let me know by when does the first training programme/ meeting for this contract need to be set or in other words by when can a vendor hope to see this contract being started operationally?	It is estimated that services will start from July 2015, with the first training courses/information days organised under this concession agreement taking place from September 2015 onwards.
5	As stated in the Technical Specifications for Service Concession document "All training sessions and information days shall be recorded and the recordings subsequently be made available for training purposes to staff at the EMA and at NCAs in EEA countries". Therefore, would it be correct to assume that these recordings can be utilised in support of other training sessions on the same topic, especially if we have used key regulatory staff to deliver some key	Yes. However, recordings may only be used in the context of the concession agreement and may not be used for any other purpose. See also Article II.5 'Ownership of copyrights' of the draft concession agreement.

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	messages?	
6	In terms of the scenarios outlined in the pricing strategy when combined with the discounts and price reductions it would appear that the training specifically for the regulators would generate no-income or only just cover costs. However, it is also stated in the Technical Specifications for Service Concession document that 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. Therefore, does the above apply to the trainings in which regulators are the only attendees?	Yes. However, the principles listed under section 3.6. ('Pricing strategy') of the technical specifications apply.
7	Could you provide clarity on "non-commercial" organisations and universities, this could be a very broad population subject to free attendance, we would assume some criteria and proof would have to be supplied, please confirm?	'Non-commercial' organisations include not-for-profit organisations like patient organisations, charities etc. 'University' refers to full-time staff and full-time students. The proof of affiliation will be at the discretion of the concessionaire.
8	Is SMEs for the purpose of the training a pre-approved list, or will the criteria be provided?	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
9	In terms of the reductions and the allocation of places on a first-come first served basis is there a cap that can be applied across the training course to balance the stakeholder numbers and to secure revenue from the initial training courses?	The technical specifications do not include a cap. The principles listed under section 3.6. ('Pricing strategy') of the technical specifications apply. All registrations shall be treated on a first-come, first-served basis.
10	If we were to submit an yearly training schedule to the EMA at the beginning of that year or the previous year for the following year (after due consultation with	The concessionaire would be encouraged to block EMA meeting rooms as soon as possible and as soon as the training schedule

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	the Agency), would it be possible to block the EMA training venues for the entire year for those days as this could have an impact on the pricing strategy.	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=W0b01ac058004d5c3)
11	In case of cancellations of the Agency venues that have been booked for training/information days, how much prior notice would be provided to the concessionaire by the Agency?	In principle, the Agency will respect its agreement when meeting rooms have been allocated for external training. 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.
12	Will VAT be charged on the venue rate per delegate?	The Agency does not charge VAT on the venue rate per delegate. However, catering expenses will be subject to VAT.
13	Is the delegate rate in the pricing grid inclusive of VAT?	Prices should be exclusive of any taxes and duties.
14	Can you confirm that the Honorarium is paid to all speakers irrespective of their background? I am aware that the current provider does not pay any compensation to speakers. Can you confirm if speaker payments are required especially for regulatory authority staff who will be key speakers?	Instructors/speakers from national competent authorities shall not be entitled to an honorarium, but to payment/reimbursement of travel and accommodation only.

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15	Do the EMA have any policy on the level of payment that would be acceptable for a member of a regulatory authority?	See response to Q14.
16	Is the draft for the Training Concession Agreement re. EMA/2014/35/RE a standard EMA draft concession agreement or is it a document prepared specifically for this EMA concession service agreement?	The draft concession agreement ref. EMA/2014/35/RE is the Agency's standard draft concession agreement.
17	As catering price is part of the tender, we need to know the prices for coffee breaks and lunches to be able to calculate the prices properly.	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 agreement.
18	In the Technical Specification it states that the requisite minimum number of participants in any given course is 10, and in case there are less than 10 participants the course shall be cancelled and re-scheduled. What is the maximum amount of time before the scheduled date of the course that the concessionaire has to ensure that the minimum of 10 participants is reached? Does the cut-off date and the cancellation decision sit with the Agency or the concessionaire? In the case the course is to be held on the Agency premises and is cancelled will the Agency charge the concessionaire the recovery costs pursuant to the Agency Policy/ 0062?	The decision and cut-off date for cancellations will be at the discretion of the concessionaire. However, as mentioned in the technical specifications, all cancellations shall be agreed with the Agency. The recovery costs pursuant to Agency Policy 0062 will only be charged for training courses and information days that were held at the Agency premises. No charges will be incurred for cancelled events.
19	Does the Agency charge the recovery costs pursuant to the Agency Policy/0062 for participants, whose course fees are waived pursuant to Section 3.6. of the Technical Specifications?	As stated in Agency Policy/0062 cost recovery applies to participants paying a full registration fee and to participants paying a reduced registration fee only.
20	Could you please specify in more detail what is meant by "Facilitate programme	During the programme development phase the concessionaire

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	committee meetings and development of the programme content" (Section 3.9.7., second bullet point of the Technical Specification), in particular, whether any reimbursement of travel expenses of the committee members is expected?	is expected to liaise with the programme committee and organise meetings, including logistics, as required. These meetings would normally take place via teleconference or via virtual meeting tools (e.g. Adobe Connect).
21	When an applicant chooses to provide part of the services through a subcontractor (no partnership, consortium other form of joint-application to be submitted), are the following documents from the subcontractor sufficient for the application: (i) letter of intent, (ii) Annex II relating to Exclusion Criteria, (iii) documents proving economic & financial capacity, (iv) authorisation to perform subcontracted part of the concession under national law, and (v) express authorization of entry in the VAT register. If any of the listed documents are not necessary, please indicate. If any other documents required from the subcontractor are missing, please specify.	The following documentation should be submitted with the application in relation to subcontractors: (1) Letter of intent (2) completed Annex II (supporting evidence shall be required from the successful applicant and its subcontractor/s only, before signature of the concession agreement) The Agency reserves the right to request at a later stage that the applicant provide documentation in relation to the selection criteria from any concession partner (relating to economic and financial capacity and/or technical and professional capacity).
22	In Section 10, under "Evidence Required", fourth bullet point, it is stated that "Applicants should also provide 3 Curricula Vitae of trainers ...", is an applicant allowed to submit more than 3 CVs of trainers, or will submitting more than 3 such CVs be considered as formal mistake, which shall lead to disqualification of the applicant?	In line with the technical specifications, applicants are requested to submit 3CVs only.
23	When applying as a consortium , we understand that only the lead of the consortium needs to provide evidence relating to professional indemnity insurance, and not all of the partners involved in the applying group?	Only the main applicant is required to provide evidence relating to professional indemnity insurance. However, the Agency reserves the right to request at a later stage that the applicant provide documentation in relation to the selection criteria (economic and financial capacity) from any concession partner.

