

EMA/186823/2023 Staff Relations and Support Department

Technical specifications for open invitation to tender

Procurement procedure EMA/2003/OP/0015 Hotel and travel booking services

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Technical specifications for open invitation to tender No. EMA/2023/OP/0015 Hotel and travel booking services

1. Title of the invitation to tender

This document contains the technical specifications for the open invitation to tender no. EMA/2023/OP/0015 for Hotel and travel booking services.

2. Purpose and context of the invitation to tender

The European Medicines Agency ("the Agency" or "EMA") is a decentralised agency of the European Union (EU) based in the Zuidas area of Amsterdam.

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

EMA:

- Supports medicines development by giving scientific advice and providing guidance to developers of medicines;
- carries out robust scientific evaluations of medicines for human use and veterinary medicinal
 products 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 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 safety, efficacy and quality 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 mandate, EMA is required to carry out business travels within and outside the European Union. The Agency estimate that it will coordinate an average of 5,200 worldwide trips per annum. Approximately 4,200 of these trips concern external experts (delegates) attending meetings at the Agency premises (99 %) and occasionally in other locations worldwide (1%). The remaining estimated 1,000 trips concern EMA staff travelling for authorised business trips (missions). Out of the estimated 1,000 missions per calendar year about 25% will be trips outside Europe (mainly USA, Africa, Japan and other Asian countries).

Additionally, approximately 9,000 hotel nights per annum are estimated to be booked for the delegates attending meetings at the Agency's premises and occasionally in other worldwide locations. Approximately further 1,000 hotel nights per annum may be required by EMA staff going on missions. Participants attending meetings and events at EMA come principally from the EU Member States but may also come from other countries. Please note that that the number of hotel and travel required fluctuates throughout the year with August usually being a quieter period. Approximately 80% of the overall hotel and travel bookings are made online via Online Booking Tool (currently Amadeus Cytric Travel) with the remaining 20% of the overall hotel and travel bookings made offline with the Travel Agent via email/phone. Currently there are approximately 2,500 user profiles set up in the Online Booking Tool (representing approximately 1,600 delegates and 900 EMA staff).

The above figures and trends are indicative only and are not binding on the Agency as a future purchase and the actual volume of services may vary depending on the needs of the Agency.

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.

3. Subject of the tender

3.1. Glossary

Term	Explanation
The Agency Cost category	The European Medicines Agency (also referred to as EMA or the Agency). Type of expenditure corresponding to two different types of travellers for whom EMA provides travel and/or hotels. For this contract, two different cost categories will be used: Delegates and Missions. Each cost category is subject to its own reimbursement rules. The cost category will be communicated to the Travel Agent by the traveller at the time of booking and it must be indicated on all bookings made.
Delegate Delegates Reimbursement Rules	External expert invited to attend meetings at EMA location or abroad. Rules for reimbursement of expenses for delegates attending meetings (Annex VIII)
EDPS Guidelines	European Data Protection Supervisor Guidelines to which the Travel Agent must adhere to, when processing data obtained in connection with this tender procedure (Annex XIII).
EMA	The European Medicines Agency (also referred to as EMA or the Agency).
EMA Staff	Employee of EMA.
Meeting	A meeting organised by EMA and attended by delegates. To enable the

Term	Explanation
	Travel Agent to validate delegates' bookings, as soon as the meeting is authorised in EMA meeting management system, EMA will provide the Travel Agent with the meeting reference number together with additional information associated with each meeting such as start/end date, time, place, list of participating delegates and their reimbursement status.
Meeting management system	Internally developed IT system for the management of EMA meetings containing information relevant meeting information such as meeting reference number, start/end date, time, place, list of participating delegates and their reimbursement status.
Meeting reference	An internal reference number, unique for each meeting attended by delegates and organised by EMA. The delegate will indicate the meeting reference when making booking with Travel Agent regardless of whether the booking is made online (in OBT) or offline (via email/phone). Relevant meeting reference must be stated on all delegates' bookings.
Member State	Member State of the European Union.
Mission	Authorised business trip of an EMA Staff member approved by EMA and coordinated by Mission team.
Mission number	An internal reference number, unique for each authorised mission. A correct mission number will be provided to the Travel Agent by the EMA staff member travelling on a mission making hotel/travel request regardless of whether the booking request is made online (in OBT) or offline (via email/phone). Mission number must be used for all bookings made for the particular mission.
Mission rules	Rules governing mission and authorised travel reimbursement (Annex IX).
Mission team	EMA Staff responsible for coordination of missions, accommodation and travel for EMA staff.
MSS team	Meetings Support Service team coordinating meetings, accommodation and travel for delegates.
OBT	Online Booking Tool (as defined in point 3.2.1)
Offline Booking Request	Travel and/or hotel booking request made with Travel Agent via email/phone
Online Booking Request	Travel and/or hotel booking request made with Travel Agent via OBT
Organisational entity	Part of EMA organisational structure. A correct organisational entity name will be communicated to the Travel Agent by the traveller and must be indicated on all travel quotes and bookings requested by EMA staff going on missions regardless of whether they are made online (in OBT) or offline (via email/phone).
Private transfer	Passenger transfer arranged by the Travel Agent with a private transport carrier (e.g. taxi) to transport delegate(s) or EMA staff travelling on a mission from/to destinations defined in offline booking request. Primarily it entails transfer between an airport/train station and a hotel/place of meeting.
Public transfer	Passenger transfer arranged by the Travel Agent with a public transport carrier to transport EMA staff or delegates primarily from a place of employment/hotel/place of a meeting to an airport/train station and vice versa.
Travel Agent	Travel management company to which the hotel and travel booking
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Term	Explanation
	contract is awarded to (also referred to as the Contractor or successful tenderer).
Travel Booking Guide for EMA Travel Agent	A guide outlining how the bookings for EMA Staff going on missions should be made (for current version see Annex XI).

3.2. Technical specifications

The Agency considers that it may require the service of an offsite Travel Agent who can provide hotel and travel booking services as well as other related services (see point 3.2.6 Additional services).

There are two types of travellers EMA will require hotels and/or travel for: Delegates and EMA staff going on missions. The Travel Agent will be notified by the traveller to which category she/he belongs at the time online or offline booking request is introduced.

The Travel Agent will be able to identify the type of traveller through either: the meeting reference provided by the delegate, or the mission number submitted by EMA Staff going on mission. If the traveller identification is inconclusive, the Travel Agent must contact dedicated team in EMA to confirm the traveller's details.

Currently approximately 80% of all travel and hotel booking requests are made online using in OBT with the remaining bookings being made offline by email/phone. It is estimated that a similar proportion between online booking requests and offline booking request will be maintained under the contract to be awarded.

It is to be noted that booking process for each type of traveller is different and subject to its own reimbursement rules. The Travel Agent will be fully trained on the Rules of reimbursement of expenses for delegates attending meetings which apply to delegates' bookings as well as on the Guide to missions and authorised travel ("Mission rules") which apply to EMA staff travelling on missions. For the above-mentioned reasons, configuration for delegates is different than OBT configuration for EMA staff travelling on missions.

The successful tenderer will provide, customise, support and maintain an Online Booking Tool (OBT) which will give the delegates and EMA staff the possibility to request hotel and travel directly from the Travel Agent using the booking tool. While the majority of the booking requests are made online, the successful tender must also be able to provide offline booking services (i.e. made by email/phone).

The Travel Agent must deliver the services as outlined in the Service overview (see point 3.2.9 Service Overview) and provide the monthly reports and statistics (see point 3.2.7 Reporting), reflecting the services delivered.

EMA will only pay for services as detailed in the costing sheet and all other services as listed in the technical specifications will be expected to be delivered as part of the overall service delivery.

3.2.1. Online Booking Tool (OBT)

The Agency will require the successful tenderer to provide, customise, support and maintain an OBT that would give the delegates and EMA Staff, the possibility to book their hotel and/or travel (i.e. online bookings). Offline bookings via email/phone will remain are estimated to be no more than 10% of the overall bookings made.

The OBT should be comprehensive, user friendly, secure, web-based and accessible from smartphones and tablets. Each OBT user must be provided an individual password protected user account.

If the OBT is (or will be) available as an application, which can be downloaded and installed on the mobile devices, the Agency will consider using such application in the future, providing it is approved by the EMA Information Security Office.

The OBT must be developed, implemented, maintained and supported by the Travel Agent in a way that EMA complies with the applicable EU data protection legislation (i.e. Regulation (EC) 45/2001¹) and any update to the legislation that might come into force during the contractual period).

In particular, the Travel Agent will need to fulfil the following requirements:

- the service provider will act as a Data Processor and meet all the obligations laid down in Article 28 of Regulation (EU) 679/2016², the GDPR, including but not limited to notification in case of data breaches, audit conducted by EMA or the European Data Protection Supervisor;
- all personal data collected by the Travel Agent via the OBT or any other data processing system, should be adequately secured;
- when the OBT is operated through a mobile app, security details of the mobile app will meet the EDPS guidelines (Annex XIII);
- data collected by the OBT should not be transferred to any third-party, and to any sub-Contractor, unless there is an explicit agreement from EMA;
- data collected by the OBT should only be processed (both at rest and in transit) in the EU;
- data collected by the OBT should be stored and processed by the service provider in accordance with retention periods established by EMA;
- the persons whose data will be collected will be informed about the processing of their personal
 data in accordance with applicable legislation, through an adequate data protection notice
 made available on the OBT;
- security of the OBT is the responsibility of the Contractor who will be responsible to implement
 the appropriate security access protocols as would be expected and updated from time to time.
 In particular all conditions must be adhered to:
 - be provided via a secure channel (https);
 - prevent unauthorised access meaning that only authenticated user can use the system;
 - prevent users to create weak passwords (minimum 12 characters);
 - lock user account after 3 to 5 unsuccessful attempts (in case wrong credentials are inserted);
 - offer password reset capabilities to end-user;
 - be accountable for OBT security incidents which should be reported to EMA immediately once discovered;
 - be compliant with security best practices such as (pen test, vulnerability assessment, Access Controls, controls to protect user's Data etc.).

The OBT currently used by EMA is Amadeus Cytric Travel. The successful tenderer will be required to assist with preparation of the change management plan including a user-friendly communication

¹ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

campaign, ensuring a smooth and successful transition to the proposed OBT, should it be different from the current one.

When the OBT proposed by the successful tenderer is fully operational, the following points will need to be fulfilled:

- The OBT must, subject to system's configuration with pre-defined set of criteria related to
 respective reimbursement rules (e.g. destination dependent hotel ceilings, mandatory field for
 meeting reference or mission number) allow users to view in real time all available hotel and
 travel (flight and train) options at the time of booking request being made;
- The OBT configuration must allow to display to the user only hotels which are within the hotel ceilings set for each country/destination by applicable reimbursement rules;
- The OBT should allow for hotel and travel invoices to be settled by the Travel Agent and billed back to EMA;
- When the hotel/travel request complies with EMA reimbursement rules, the Travel Agent should proceed with the booking, confirm the request directly to the traveller and deal with any follow up questions and queries relating to the booking;
- As soon as the booking is made, the traveller and EMA should be provided with an individual
 electronic (but printable) summary of hotel and/or travel arrangements made for each trip. The
 individual summary/ confirmation must indicate traveller's name, reservation details as well as
 meeting reference or mission number;
- The Travel Agent will adjust and update the tool during the duration of the contract as and when needed (e.g. amend the hotel ceilings displayed in the tool if EMA reimbursement rules change)
- The tool should be user-friendly and the Travel Agent should provide a non-premium number helpline and user manual in English;
- In instances when the OBT is not available, the Travel Agent should process bookings via email and non-premium phone number;

The OBT and its delivery, implementation, maintenance, support, update and any periodic adjustments, should be provided as a part of the overall service delivery. Any expenses that might apply to fulfil the requirements outlined in this point 3.2.1, must be included in the prices for services quoted in the costing sheet, as the Agency does not expect to pay for the OBT related costs separately.

3.2.2. Delegates booking process

- Meeting will be authorised in Agency's internal meeting management system. To enable the
 Travel Agent to validate delegates' bookings, EMA will provide the Travel Agent with all
 information relevant to the meeting such as meeting reference number; meeting start/end date
 and time; place of the meeting; list of participating delegates together with their place of origin
 and reimbursement status as well as any other relevant information. In case of changes (e.g.
 additional delegates) EMA provides updated information to the Travel Agent;
- EMA will send to the delegate a meeting invitation indicating the meeting reference, meeting details (e.g. start, finish and location) and reimbursement status;

- Delegate will introduce online (via OBT) or offline (via email/phone) booking request. Both, online and offline booking requests must include meeting reference before they can be actioned;
- Travel Agent will action online and offline made booking requests by:
 - Booking hotel and/or travel if the request complies with Delegates reimbursement rules
 (Annex VIII)
 - Contacting the delegate for clarification if:
 - Additional information is needed to process the booking;
 - Multiple hotel/travel options are available for the same booking criteria and price;
 - Requested hotel/travel are not available but a suitable alternative exists;
 - Hotel/travel request does not comply with Delegates reimbursement rules
 (Annex VIII) and the Travel Agent needs to determine:
 - if the delegate has grounds for reimbursement rules deviation, in which case the Travel Agent will contact EMA for confirmation and decision;
 - if the delegate has no grounds for reimbursement rules deviation, but wishes to accept a complying alternative suggested by the Travel Agent, in which case the booking will be processed by the Travel Agent;
 - if the delegate has no grounds for reimbursement rules deviation and does not wish to accept complying alternative suggested by the Travel Agent, in which case the Travel Agent will contact EMA for decision;
 - o Contacting EMA for confirmation and decision if:
 - The delegate states that there are grounds for reimbursement rules deviation;
 - Initial hotel/travel request does not comply with Delegates reimbursement rules but there are no grounds for reimbursement rules deviation and either, there are no available alternatives complying with the reimbursement rules or the delegate does not wish to accept available alternative suggested by the Travel Agent;
 - Individual case is not clear;
 - Confirming the booking directly to the delegate and provide EMA with an electronic (but printable) summary of hotel/travel arrangements made indicating traveller's name, reservation details and meeting reference.

Amendments and cancellations

• Travel Agent should process any amendments or cancelations send by the delegate if they have no financial impact or do not deviate from the reimbursement rules;

- Travel Agent should provide EMA with an electronic confirmation of such amendment or cancellation including a brief reason for the change;
- Travel Agent must contact EMA for confirmation on how the amendment or cancellation requested by the delegate should be processed, if it has any financial impact or results in deviating from the Delegates reimbursement rules;

Following the award of the contract, the Travel Agent will be fully trained on Delegates reimbursement rules (**Annex VIII**). During the first three months of the contract, the Travel Agent will be extensively supported by the Agency's MSS team to ensure good understanding of Delegates reimbursement rules as well as correct configuration of the proposed OBT for delegates. Following the three-month period, all subsequent training of Contractor's staff will be the responsibility of the Contractor, which will ensure that all members of its staff assigned to this contract possess the necessary knowledge to provide the relevant services.

Any future revised version of these rules will be transmitted to the Contractor and shall repeal and replace the existing ones. The adopted rules shall then automatically form an integral part of the contract.

After the three-month period, the Travel Agent will be financially responsible for the online and offline bookings made by delegates which were confirmed by the Travel Agent and do not comply with Delegates reimbursement rules and where prior authorisation for deviation from the rules was not granted by EMA i.e. the Travel Agent will have to correct the booking at its own expense.

3.2.3. Mission booking process

- EMA Staff going on missions will request a travel quote from the Travel Agent by e-mail. Travel quote will be requested by using a dedicated e-mail form (see **Annex XI**) indicating the location and start/end date of mission. Alternatively, and if possible, staff member may obtain a quote with a suitable travel arrangement available in OBT, for example by generating a PDF file right before the travel booking request in OBT is confirmed (current EMA practice);
- When requested, the Travel Agent will have to prepare the quote(s) as per guidelines provided
 by the Mission team (see **Annex XI** for current version); EMA Staff going on missions will use
 the quote(s) to internally authorise mission and to obtain the mission number;
- EMA staff member going on missions will introduce online (via OBT) or offline (via email/phone) hotel/travel booking request;
- For online hotel/travel requests: OBT's configuration must include a mandatory field for
 mission number to be provided by the EMA staff member and it must show only hotels that
 comply with the hotel ceilings set by the Mission rules. No further validation of online booking
 requests (i.e. compliance with Mission rules) by the Travel Agent is required before OBT issues
 booking confirmation;
- For offline travel request: Travel Agent will have to first check if the booking request sent by EMA staff going on missions is accompanied by the mission number and check that request complies with Mission rules (e.g. requested hotel rate complies with destination ceiling).
 Subsequently, the Travel Agent will process the booking.
- For offline hotel booking request exceeding Mission rules ceilings:
 - Requests accompanied by a specific authorisation issued by EMA should be processed by the Travel Agent;

- Requests not accompanied by a specific authorisation issued by EMA may still be processed but the Travel Agent must directly charge the staff member the amount exceeding the respective hotel ceiling;
- Travel Agent / OBT will confirm the booking directly to EMA and EMA staff going on a mission and provide an electronic (but printable) confirmation of hotel/travel arrangements made indicating traveller's name, reservation details and mission number;

Amendments and cancellations

- Travel Agent will process any amendments or cancelations send by EMA staff going on a mission if they have no financial impact or do not deviate from the Mission rules;
- Travel Agent must contact EMA staff going on a mission if the requested amendment or cancellation has any financial impact or results in deviating from the Mission rules;
- EMA staff going on a mission will check internally if extra expenditure can be made and obtain a written confirmation should the change/cancellation be authorised;
- Travel Agent will process the amendment/cancellation having any financial impact or deviating
 from the Mission rules if the traveller's request is supported by written authorisation form EMA
 (samples of an acceptable approval will be communicated to the Travel Agent);
- If the amendment/cancellation having any financial impact or deviating from the Mission rules is not supported by a written authorisation, it will be processed by the Travel Agent only if any additional cost can be charged directly to the traveller;

Following the award of the contract, the Travel Agent will be fully trained on Mission rules (**Annex IX**). During the first three months of the contract, the Travel Agent will be extensively supported by the Agency's Mission team to ensure good understanding of Mission rules as well as correct configuration of the proposed OBT for EMA staff travelling on missions. Following the three-month period, all subsequent training of Contractor's staff will be the responsibility of the Contractor, which will ensure that all members of its staff assigned to this contract possess the necessary knowledge to provide the relevant services.

Any future revised version of these rules will be transmitted to the Contractor and shall repeal and replace the existing ones. The adopted rules shall then automatically form an integral part of the contract.

After the three-month transitional period, the Travel Agent will be financially responsible for the offline mission bookings request made by EMA staff and confirmed by the Travel Agent which do not comply with Mission rules and where prior authorisation for deviation from the rules was not granted by EMA i.e. the Travel Agent will have to correct the bookings at its own expense. The responsibility for online made mission bookings complying with the Mission rules will remain with the EMA staff travelling on a mission.

3.2.4. General requirements

- Booking, amending, cancelling and issuing tickets for all air, rail, sea and road travel, should be
 made at the best possible price (combining the most direct and least expensive routes to
 achieve cost effectiveness).
- Provided the trip starts and finishes at the same place, the travel ticket should, subject to the carrier's ticketing system, be by default issued as a return ticket i.e. only one transaction fee is to be charged for issuing a return ticket. Should the carrier's ticketing system (e.g. train companies) or proposed travel arrangement (e.g. exceptional use of two different airlines for

- one return trip) not allow issuing a return/combined ticket, the Agency accepts that two separate one-way tickets may need to be issued with each incurring a transaction fee.
- As soon as the booking is made, the traveller and, where applicable, MSS team should be
 provided with an individual electronic (printable) summary/confirmation of hotel and/or travel
 arrangements made for each trip. This individual summary confirming the arrangements made
 should indicate traveller's name, reservation details and either meeting reference or mission
 number. For online booking requests the summary of what has been booked should be
 generated by OBT and send by email to the traveller and, where applicable, MSS team. For
 offline booking requests, the Travel Agent should send the email confirmation to the traveller
 and, where applicable, MSS team.
- Travel Agent must be able to purchase low-cost airline tickets.
- All accommodation arrangements must be secured within the hotel ceilings stated in the Delegates reimbursement rules and Mission rules (Annex VIII and Annex IX respectively).
- Travel Agent will by default have to settle the travel/accommodation cost directly with the airlines/hotels and invoice EMA for such cost as outlined in point 10 of these Technical Specifications (Payment arrangements).
- Travel Agent must also be able to book accommodation where the traveller will be able to settle his/her own account, for example for non-reimbursed delegates.
- If a delegate or EMA Staff going on a mission decides to book accommodation at a higher rate than indicated in the reimbursement rules (Annexes VIII and IX) and prior authorisation is not granted by EMA, the Travel Agent must charge the difference directly to the delegate or EMA staff i.e. EMA should be invoiced only up to the applicable hotel ceiling.
- It should be possible for another authorised person (e.g. assistant) to book flights and/or hotels on behalf of the delegate or EMA staff travelling on a mission.
- In case airlines or hotels make available credit point systems or similar frequent user reward schemes, the Travel Agent will manage the use of these rewards in the most beneficial way for the Agency, giving the Agency access to free tickets, free hotel nights, free services or other benefits.

3.2.5. Specific requirements

Delegates

 The Travel Agent should ensure that the Agency benefits from negotiated corporate rates with hotels primarily in the immediate vicinity of EMA headquarters in Amsterdam and at Schiphol Airport. On some occasions the Travel Agent may be asked to negotiate corporate rates with hotels worldwide. Corporate rates negotiated by the Travel Agent may not exceed the hotel ceilings set by Delegates reimbursement rules.

The Agency however reserves the possibility to negotiate corporate rates and special agreements directly with hotels, in which case it will communicate to the Travel Agent such agreements. The Travel Agent will then be required to book according to those agreed terms.

The cost of the hotels (excluding the fees for hotel reservations) must be fully passed on to the hotels without Contractor claiming any deductions (e.g. commission for the nights booked at the particular hotel on behalf of the Agency). Any profit Contractor wishes to make from hotel

- reservations made on behalf of the Agency must be included in the transaction fees for hotel reservations made through OBT or via/email/phone as stated in the Costing sheet in Annex II.
- Mandatory cancellation policy for hotels with negotiated preferential rates: Provided reservation
 is cancelled at least 24 hours in advance, there should be no charge for the hotel cost to the
 Agency.

EMA staff travelling on missions

- Before the booking is made, EMA Staff going on Missions will require the travel quotes indicating the following points:
 - o first and last name (as per passport) of the traveller;
 - mission number communicated by EMA staff;
 - o itinerary details indicating flight/train/boat dates and times of departure and arrival;
 - ticket class;
 - baggage allowance;
 - o information on ticket flexibility and potential cost of change/cancellation.
- The travel quote should be provided by Travel Agent by email when booking is made offline.
- Accommodation cost should exclude breakfast, or if breakfast is offered as a part of a specific deal, the price should be stated separately
- All OBT profiles must be set up using solely the EMA email addresses of employees (i.e. no private email addresses can be used for this purpose)

3.2.6. Additional services

Public transfers

The Travel Agent must be able to book a public transfer for EMA travellers offline for a service fee stated in the Costing sheet in **Annex II**. Should the OBT allow some possibility of booking a public transfer (e.g. train between Amsterdam Central Station and Schiphol or Den Haag and Schiphol), such booking should be billed to the Agency for a service fee in the Costing sheet in **Annex II** corresponding to the fee for booking European continental train.

Private transfers

The Travel Agent must be able to book a private transfer for EMA travellers offline for a service fee stated in the Costing sheet in **Annex II**. The Agency foresees that private transfers will only be booked in exceptional circumstances which include but are not limited to:

- · Strikes of public transport companies;
- Business continuity situations;
- Travel to a destination where there is either no public transport or public transport options are extremely limited;
- Travel to a destination where enhanced security of EMA travellers is required (e.g. EMA staff or delegates travelling to Africa).

The cost of the private transfer is to be paid by the Travel Agent and subsequently invoiced to the Agency with a corresponding transaction fee.

Visa services

When a traveller needs to obtain a visa to travel, the Travel Agent will be responsible for the relevant procedures to obtain the visa from the authorities responsible for issuing it.

For the staff members to represent the Agency in an official capacity they need to obtain either the business visa or the diplomatic visa. Non-EU countries have their own processes e.g. for to the USA, the Travel Agent should, with the support of the Agency, provide assistance with obtaining the A2 diplomatic visa.

The Travel Agent will perform all necessary steps within its control to obtain the visa before the departure date and, if necessary, it will pay the visa fees in advance, for which it will subsequently invoice the Agency.

For indicative purposes, it is estimated that approximately 30 visa requests may be needed per year.

Other services the successful bidder will also be required to perform are:

- Advising the Agency by form of email alerts on specific location information for travellers and any disruptions related to travel, whether by air, train, public transport, etc.
- Upon Agency's request the successful tenderer may be required to cooperate with Agency's Contractor specialised in the field of travel security, especially with regards to transfer of travel bookings data.

3.2.7. Reporting

The Travel Agent must provide monthly reports and statistics reflecting the services delivered to the Agency under this contract. Statistics need to be comprehensive, easily understandable and all reports must be in English.

Two different types of travellers (delegates and EMA staff travelling on missions) correspond to two different cost categories. Therefore, monthly figures and statistics will have to be provided separately for Delegates travel and Mission travel.

The Travel Agent will have to provide regular reports indicating usage rate between online bookings made via the OBT vs offline bookings made by email/phone.

Detail guidelines, requirements and templates will be supplied to the Travel Agent by EMA as the Agency requires detailed information on monthly hotel and travel bookings.

The Agency must also receive monthly a specific report per cost category (i.e. Delegates and Missions) on total carbon footprint, indicating it separately for all train journeys and all flights taken in the respective reporting month. Additionally, the overview of flights carbon footprint should also be subdivided into long haul, medium haul and short haul flights. The data required for train and air travel must indicate CO2 (kg) and distance (km).

3.2.8. Environmental Considerations

- When distances allow, a priority should be given to travel by train over travel by plane. Consider, whenever possible, travel by train instead of air travel if corresponding travel by train does not exceed 4 hours e.g. Amsterdam Brussels, Paris etc.
- In the case of air travel that allows it, give priority to non-stop direct flights.

- Prefer carriers that declare and demonstrates projects regarding CO2 emissions, for example:
 - certified CO2 emission reduction programmes;
 - certified CO2 offsetting projects (carbon offsetting);
 - use as a % of the– of sustainable fuels for aviation (SAF Sustainable Aviation Fuel);
 - actions to reduce the environmental impacts of flights, e.g. limit food waste and reduce the use of plastic;
 - guarantee a more recent aircraft fleet that allows for fuel savings (e.g. Airbus 321
 NEO-New Engine Option, Airbus 350);
- Prefer hotels which are certified as environmentally friendly (EMAS, Green Key, EU Ecolabel, ISO 14001 or similar).
- For environmental and cost reasons, the tickets must be issued electronically (e-tickets).

3.2.9. Service Overview

- The working language of the Agency is English, and the tenderer must assure its capability to effectively communicate with the Agency in English. This is crucial for the smooth execution of all services outlined in the contract, encompassing obligations stemming from regulatory compliance like Health and Safety and Data Protection, as well as for the efficient and timely response in respect to contract management;
- During the Agency working hours, the response to requests shall be provided by e-mail, telephone or through the OBT within 3 hours and in case of urgency within one hour;
- The Contractor must provide a dedicated team to serve the Agency as well as a dedicated nonpremium telephone number and e-mail address to be used for communication with the Agency and its staff;
- The Contractor shall guarantee enough resources to support via e-mail, telephone and OBT the
 volume of activities during normal EMA working hours on each Agency working day. Therefore,
 replacement of staff for any reason (sickness, holiday, training, etc.) must be foreseen by the
 Contractor at their own cost;
- The Contractor shall ensure that all members of its contract implementation/support team
 involved in the provision of services to the Agency have the necessary and sufficient
 knowledge (e.g. respective reimbursement rules and other internal Agency's procedure as
 communicated to the tenderer) and training to provide the services at the level required;
- The hotel and travel services should be provided during all EMA working days and during EMA's working hours (Monday to Friday from 09h00-18h00). No services will be required on the Agency holidays (Annex XII). It should be noted that Agency holidays do not coincide exactly with the national bank holidays of the Netherlands where EMA is located;
- The Contractor must have an emergency out of hours service for EMA staff and delegates outside the normal EMA working hours. This service must be available in English on a 24/7 basis and not use the premium telephone numbers.
- The Contractor (including the emergency service) should be knowledgeable of the <u>European</u>

 <u>Passenger Rights Directive</u> in order to provide advice when an emergency situation is covered

by the Contractor and when the traveller should contact the immediate service provider e.g. carrier, and provide advice upon where to seek further information.

- The successful tenderer will be required to attend a number of virtual meetings with the Agency:
 - Initial meetings at the start of the contract in order to customise and set up the OBT and, if required, to develop the implementation strategy and change management plan;
 - Quarterly contract performance review meetings;
- The Agency will appoint a member of its staff as a contract manager for this service contract.
 The contract manager will be the main contact person for all issues relating to the
 implementation of the contract and will work with the Travel Agent on customisation,
 implementation and fine tuning of the proposed OBT;
- The Travel Agent must immediately and unconditionally hand over all information and traveller profiles collected during the course of the contract through the OBT or any other means, at any time EMA so requests, and in any event at the end of the contract, to a new Travel Agent designated by the Agency;
- A draft Service Level Agreement has been included in **Annex XV** but the final comprehensive version of SLA will be finalised following the three-month transitional period.
- The outgoing Contractor will be responsible for the complete hand-over of all pertinent files
 and information as defined by the Agency during the overlap period (estimated to be one
 month).

3.3. Minimum requirements to be met by the tender

The following minimum requirements must be met by the tender for it to be considered compliant with the technical specifications. Tenderers 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 procurement 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.
- The working language of the Agency is English, and the tenderer must assure its capability to
 effectively communicate with the Agency in English. This is crucial for the smooth execution of all
 services outlined in the contract, encompassing obligations stemming from regulatory compliance
 like Health and Safety and Data Protection, as well as for the efficient and timely response in
 respect to contract management;
- Processing of personal data in connection with this service must comply with EU data protection legislation, in particular, Regulation (EU) 2016/679 (General Data Protection Regulation), in such a manner that processing of personal data will meet the requirements of Regulation (EU) 2018/1725.
- Compliance with the requirements for the hotel and travel booking services listed in point 3.2. (including the subsequent sub-points) of these technical specifications.
- Compliance with the invoice requirements as specified in point 10 Payment arrangements of these technical specifications.

3.4. Place of performance

The services will be performed at the following locations: the Contractor's premises.

4. Participation in the tender

4.1. Agreements on public procurement

Participation in procurement procedures 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.

Participation in procurement procedures is also open to international organisations as defined in article 156(1) of Regulation (EU, Euratom) 2018/1046.

The rules of access to the market do not apply to subcontractors.

The procurement procedures of the Agency however are not open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA"). For the avoidance of doubt, participation in EMA procurement procedures is also not open to tenderers from non-EU countries even though they have ratified the GPA because EMA is not a procuring entity as covered by the said GPA.

4.2. Joint tenders

A joint tender is a situation where a tender is submitted by a group (with or without legal form) of economic operators regardless of the link they have between them. The group as a whole is considered a tenderer³.

All members of the group assume joint and several liability towards the Agency for the performance of the contract as a whole.

Group members must appoint a Group leader and a single point of contact authorised to act on their behalf in connection with the submission of the tender and all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature. The model power of attorney attached in **Annex V** is to be used.

The joint tender must clearly indicate the role and tasks of each member and of the Group leader who will act as the Agency's contact point for the contract's administrative or financial aspects and operational management. The Group leader will have full authority to bind the group and each of its members during contract execution. If the joint tender is successful, the Agency shall sign the contract with the Group leader, authorised by the other members to sign the contract on their behalf via power of attorney drawn up in the model attached in **Annex V**.

Changes in the composition of the group during the procurement procedure (after the submission deadline and before contract signature) are not permitted unless explicitly authorised by the Agency.

³ References to *tenderer* or *tenderers* in this document shall be understood as covering both sole tenderers and groups of economic operators submitting a joint tender.

4.3. Subcontracting

Subcontracting is the situation where the Contractor enters into legal commitments with other economic operators which will perform part of the contract on its behalf. The Contractor retains full liability towards the Agency for performance of the contract as a whole.

The following shall not be considered subcontracting:

- (a) Use of workers posted to the Contractor by another company owned by the same group and established in a Member State ("intra-group posting" as defined by Article 1, 3, (b) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
- (b) Use of workers hired out to the Contractor by a temporary employment undertaking or placement agency established in a Member State ("hiring out of workers" as defined by Article 1, 3, (c) of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services).
- (c) Use of workers temporarily transferred to the Contractor from an undertaking established outside the territory of a Member State and that belongs to the same group ("intra-corporate transfer" as defined by Article 3, (b) of Directive 2014/66/EU on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer).
- (d) Use of staff without employment contract ("self-employed persons working for the Contractor"), without the tasks of the self-employed persons being particular well-defined parts of the contract.
- (e) Use of suppliers and/or transporters by the Contractor, in order to perform the contract at the place of performance, unless the economic activities of the suppliers and/or the transporting services are within the subject of this call for tenders (see Section 1.4).
- (f) Performance of part of the contract by members of an EEIG (European Economic Interest Grouping), when the EEIG is itself a Contractor or a group member.

The persons mentioned in points a), b), c) and d) above will be considered as "personnel" of the Contractor as defined in the contract.

All contractual tasks may be subcontracted unless the technical specifications expressly reserve the execution of certain critical tasks to the sole tenderer itself, or in case of a joint tender, to a member of the group.

If the tenderer envisages subcontracting any part of this contract, **Annex VI** should be completed indicating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor. subcontractor

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

A completed **Annex I** and **Annex III** is required by each subcontractor where more than 10% of the contract per subcontractor shall be executed by subcontractors.

Tenderers 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 tenderer does not intend subcontracting.

Changes concerning subcontractors identified in the tender (withdrawal/replacement of a subcontractor, additional subcontracting) during the procurement procedure (after the submission deadline and before contract signature) require the explicit authorisation of the Agency.

5. Additional documentation available to tenderers

Further information about the work of the Agency can be obtained on its website: http://www.ema.europa.eu.

6. Site visit - Not Applicable

7. Variants - Not Applicable

8. Estimated contract volume

An indicative estimate of the volumes to be ordered yearly is given in the costing sheet in **Annex II**. These volumes are estimates only and there is no commitment as to the exact quantities to be ordered. The actual volumes will depend on the quantities, which the contracting authority will order through specific contracts and order forms. In any case, the framework contract ceiling, i.e. the maximum amount to be spent under the framework contract for, shall not be exceeded.

The framework contract ceiling shall be determined as follows.	
Total amount of successful tenderers financial tender for yearly estimated volume of purchases x 4	ТВС
The estimated contingency for the cost of hotels, travel tickets, cost of private transfers and visa fees based on volumes in the costing sheet in Annex II is EUR 4,987,746.10 \times 4.	EUR 19,950,984.40
Subtotal	TBC
Contingency for price indexation and for anticipated revision of Mission and authorised travel rules +13.2%	TBC
Framework contract ceiling over 4 years	TBC

The published estimate value under section 2.1.3 of the contract notice of EUR 23,000,000.00 is based on an estimation of all the elements presented in the table above.

The Agency may exercise the option to increase the contract financial ceiling at a later stage via negotiated procedure for the repetition of similar services in accordance with Article 11.1(e) of Annex I to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union. This procedure may only take place at the latest during the three years following contract signature and shall be triggered by the need to increase the financial ceiling up to a maximum of 50% of the initial ceiling.

9. Price

9.1. Currency of tender

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

9.2. All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include delivery, supply and installation, customisation, maintenance, reporting, training etc). Prices submitted in response to this tender must also include any mobilisation cost foreseen by the tenderers including but not limited to set up of the infrastructure necessary for the implementation of the contract including OBT configuration, set up of the Contractor's work force; assistance with preparation of the change management plan including a user friendly communication campaign ensuring a smooth and successful transition to the proposed OBT (if different from the current OBT). No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

9.3. Price revision

Please see articles I.5.2 and II.20 of the draft contract (Annex VII).

9.4. Costs involved in preparing and submitting a tender

The Agency will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

9.5. Period of validity of the tender

Tenderers must enclose a confirmation that the tender (including prices) is valid for six months from the closing date for receipt of tenders.

9.6. 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. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

10. Payment arrangements

In accordance with the contract, payments shall be made in arrears following receipt of a collated invoice and completion of services, <u>on a weekly basis</u> or longer as may be agreed between the parties. Confirmed travel and hotel bookings must be invoiced as soon as they are processed, in the following billing cycle.

Payments shall be made within 30 days of receipt of the request for payment and shall be deemed to have been made on the date on which they are debited to the Agency's account. The Agency may, however, after giving notice to the tenderer, defer payment if the products or services covered by the request for payment are contested by the Agency.

The Agency reserves the right to only pay for the bookings complying with the respective reimbursement rules as set out in these technical specifications (see points 3.2.2 and 3.2.3). If after the three-month transitional period the Travel Agent applies reimbursement rules incorrectly, it will need to amend the boking, so the reimbursement rules are adhered to and any additional cost resulting from such a mistake shall be borne by the Travel Agent. If an amendment is not possible, a new booking needs to be made and the Travel Agent will bear the cost of the incorrect booking.

All invoices shall be sent to the following e-mail addresses:

- o For delegates: <u>delegatereimbursements@ema.europa.eu</u>
- o For missions: missioninvoices@ema.europa.eu

The Agency shall be bound to comply with payment periods only if requests for payment are properly presented at the above addresses.

For each cost category (i.e. Delegates and Missions separately) the Travel Agent must provide for payment a separate collated invoice for each type of service (i.e. train travel; plane travel, hotels) in PDF format. Each collated invoice must then be accompanied by a breakdown of the charges covered by the respective collated invoice (in Excel and PDF).

Collated invoice in PDF format (to be grouped by type of service i.e. plane travel, train travel and hotels) must include:

- Invoice date and number
- EMA's details (e.g. address)
- Contractor's full name and address
- · Business registration number
- VAT registration number
- A reference to the contract number
- If applicable, a reference to the Agency's purchase order number which shall be communicated beforehand
- Contractor's bank details
- Service description (e.g. Hotel accommodation for EMA delegates)
- · Net amount invoiced in EUR
- Taxes incl. VAT applied, if any, or, whenever appropriate, a note that the services rendered
 under the contract are exempt from VAT in accordance with the national tax law by which the
 tenderer is governed.
- Total amount requested for payment in EUR

Breakdown of the charges i.e. summary of the individual bookings covered by collated invoice (PDF and Excel format) must include:

- Reference to the collated invoice: date and invoice number
- Travel Agent's internal booking reference
- Supplier's name (e.g. airlines, train service provider or hotel)
- Meeting reference (for delegates) or mission number (for missions)

- Traveller's name
- Organisational entity of the EMA staff travelling (for missions only)
- Taxes (if applicable)
- Transaction fee
- Total amount requested for payment in EUR
- Additional information for travel only:
 - o Country and city of origin
 - o Itinerary details: destination country/city, dates and times of departure/arrival
 - Class of travel and associated business justification if flight not booked in economy
 - Price per ticket (for travel only)
- Additional information for hotels only:
 - Check in and check out dates
 - Place of stay
 - o Duration of stay in number of nights
 - Room type
 - o Price per hotel night

The Agency currently uses SAP accounting system in order to process all payments and a suggested Excel template with SAP upload sheet will be provided to the successful tenderer

11. Contractual details

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

The Agency wishes to conclude a single framework contract. A framework contract establishes a mechanism for future repetitive purchases by the contracting authority to be awarded in the form of specific contracts or order forms (simplified form of a specific contract). The signature of a framework contract does not impose an obligation on the contracting authority to conclude specific contracts or order forms with a framework contractor.

The single framework contract will be concluded with one contractor. Specific contracts or order forms shall be awarded on the basis of the terms laid down in the framework contract, refined to reflect the particular circumstances of the specific contract or order form. The details are set out in the draft framework contract.

The framework contract resulting from this call for tenders will be concluded for at most 48 months. The details of the initial contract duration and possible renewals are set out in the draft contract.

The Agency processes personal data in accordance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. Under the service contract the Contractor is required to comply with the provisions of EU data protection legislation, in particular, Regulation (EU) 679/2016 on the protection of natural persons with regard to the processing of personal data and

on the free movement of such data ("GDPR") in such a manner that processing of personal data will also meet the requirements of Regulation (EU) 2018/1725.

In particular, under the service contract the Contractor will act as a data processor and shall comply with the obligations laid down in Article 29 of Regulation (EU) 2018/1725 and shall provide sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing of personal data will meet the requirements of Regulation (EU) 2018/1725 and ensure the rights of the data subject.

In relation to the data processing activities the contractor carries out under this service, no transfer of personal data may be carried out by the contractor to any third party, unless instructed by the Agency to do so in writing.

The European Commission Standard Contractual Clauses between controller and processor can be found in Annex XIV and serves as the data protection addendum between EMA and the awarded tenderer.

12. Evaluation and award

The evaluation of the tenders that comply with the submission conditions will consist of the following elements:

Check if the tenderer has access to procurement (see Section 4.1.);

- Verification of administrative compliance (if the tender is drawn up in one of the official EU languages and the required documents signed by duly authorised representative(-s) of the tenderer);
- · Verification of non-exclusion of tenderers on the basis of the exclusion criteria;
- Selection of tenderers on the basis of selection criteria;
- Verification of compliance with the minimum requirements specified in the procurement documents;
- Evaluation of tenders on the basis of the award criteria.

The Agency will evaluate the abovementioned elements in the order that it considers to be the most appropriate. If the evaluation of one or more elements demonstrates that there are grounds for rejection, the tender will be rejected and will not be subjected to further full evaluation. The unsuccessful tenderers will be informed of the ground for rejection without being given feedback on the non-assessed content of their tenders. Only tenderer(s) for whom the verification of all elements did not reveal grounds for rejection can be awarded the contract.

The evaluation will be based on the information and evidence contained in the tenders and, if applicable, on additional information and evidence provided at the request of the Agency during the procedure. If any of the declarations or information provided proves to be false, the Agency may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria the Agency may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

13. Exclusion criteria

The objective of the exclusion criteria is to assess whether the tenderer is in any of the exclusion situations listed in Article 136(1) of Regulation (EU, Euratom) 2018/1046.

Tenderers found to be in an exclusion situation will be rejected.

As evidence of non-exclusion each tenderer shall provide with its tender 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.

The initial verification of non-exclusion of tenderers will be done on the basis of the submitted declarations and consultation of the <u>European Union's Early Detection and Exclusion System</u>. The documents mentioned as supporting evidence in the Declaration on Honour need to be provided whenever requested and where this is necessary to ensure the proper conduct of the procedure within a deadline given by EMA.

The Appendix to this document specifies which of the involved entities participating in the tender need to provide the Declaration on Honour and, when requested by the Agency, the supporting evidence.

The documents mentioned in the Declaration on Honour as supporting evidence on non-exclusion **must be provided with the tender submission.**

At any time during the procurement procedure, the contracting authority may request information on natural or legal persons that are members of the administrative, management or supervisory body or that have powers of representation, decision or control, including legal and natural persons within the ownership and control structure and beneficial owners, and appropriate evidence that none of those persons are in one of the exclusion situations referred to in Section A point (1) (c) to (f) of the Declaration on Honour.

It should be noted that a request for evidence in no way implies that the tenderer has been successful.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above in the following situations:

- if such evidence has already been submitted to it for the purposes of another procurement
 procedure of EMA 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 tenderer 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;
- If such evidence can be accessed by EMA on a national database free of charge, in which case the
 economic operator shall provide the Agency with the internet address of the database and, if
 needed, the necessary identification data to retrieve the document.

14. Selection criteria: legal and regulatory capacity

14.1. Requirement

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

14.2. Evidence required

All tenderers shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their tender response, stating that they have the legal and

regulatory capacity to pursue the professional activity needed for performing the contract to meet the requirement as stated in **14.1**.

The tenderer shall provide the following evidence listed below with the tender submission:

 Authorisation to perform the contract 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.

15. Selection criteria: financial and economic capacity

15.1. Requirement

- Tenderers must be financially feasible and in a stable financial position and have the economic and financial capacity to perform the contract.
- The average annual turnover of the tenderer for the last two financial years must be of a minimum value of 8,000,000 Euro.
- 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.

15.2. Evidence required

All tenderers shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their tender response, stating that they fulfil the applicable financial and economic criteria set out in **15.1**.

If the tenderer 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, including from subcontractors if requested, with the tender submission:

- 1. financial statements or their extracts for the last two financial years for which accounts have been closed;
- 2. a statement of overall turnover for the last two financial years available.

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

If the tenderer 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 contract at the disposal of the tenderer for the period of the contract may be requested by the Agency. In such case the Agency may require that the successful tenderer(s) and such entities are jointly liable for the execution of the contract.

The Agency may waive the obligation of a tenderer 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:

Davis	F	Scoring			
Ratio	Formula	0	1	2	
Liquidity	Liquidity <u>Current assets – Stocks – Debtors > 1 year</u> Short term debts	Below 50%	Between or equal 50% and 100%	Above or equal 100%	
Solvency	<i>Financial independence</i> <u>Own funds</u> Total liabilities	Below 20%	Between or equal 20% and 40%	Above or equal 40%	
	<i>Debt ratio</i> <u>Own funds</u> 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%	
	<i>Profitability</i> <u>Gross operating result</u> 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 tenderer 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 contracting authority considers appropriate.

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

16. Selection criteria: technical and professional capacity

16.1. Requirements

In case of joint requests to participate and subcontracting the evaluation shall be made as follows:

Individual assessment

• Requirement no.1: The interested economic operator and the proposed personnel shall not have any conflicting interest or conflict of interest within the meaning of Article II.1 of the draft framework contract (Annex VII), which could affect the performance of the services of the contract. It follows that the interested economic operator shall not be in any situation that could compromise the impartial and objective performance of the contract with regard to the rendition of the services.

Consolidated assessment

• **Requirement no.2**: Relevant experience in the provision of hotel and travel booking services, similar to the services as described in Section 3 of these specifications, which meets all of the following requirements:

- a) The tenderer must have extensive and demonstrable experience in the travel management field and the professional capacity to perform the contract and must have handled within the last three years at least three contracts of a similar size and nature as described these technical specifications.
- b) The tenderer must have the booking tool to process and issue flight tickets as well as national and international train tickets and hotel bookings.
- c) The tenderer must be adequately staffed to provide for a smooth and efficient performance of the tasks required in this invitation to tender, i.e. have at least one experienced contract manager and at least three experienced travel booking staff who could be dedicated to the implementation of the Agency contract. Furthermore:
 - The proposed contract manager mush have at least five years of experience in the field of providing national and international travel services, out of which three years must have been working as contract/account manager.
 - Each of the staff members proposed for the travel booking role must have at least three years of experience in the field of providing national and international travel services including the use of booking systems.
- d) The tenderer must have at least two years' professional experience in processing of large amount of personal data in compliance with Union data protection legislation, related to the subject of this tender especially where personal data are processed, in particular, in electronic databases/digital infrastructure; for example, passenger profiles, identification documents, travel plans.

Tenderers must meet <u>all</u> of the above requirements.

In case of joint tenders and subcontracting the evaluation shall be made as follows: the selection criteria shall be evaluated in relation to the tender submitted as a whole, including all consortium members and subcontractors.

16.2. Evidence required

All tenderers shall provide a declaration on their honour (see **Annex III**), duly signed and dated by an authorised representative, as part of their tender response, stating that they fulfil the applicable technical and professional criteria set out in '16.1 Requirements'.

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

The tenderer shall provide the documents listed below with the tender submission.

- In the context of requirements listed in point a) above, a list of the principal services provided in the past three years under at least three contracts, with the following information per each contract: contract value, dates and clients, public or private accompanies upon request by statements issued by the clients;
- In the context of requirements listed in point b) above, a description of booking systems and other operational facilities available to the tenderer for performing a service contract;
- In the context of requirements listed in point c) above, the educational and professional
 qualifications, skills, experience and expertise of one contract manager and at least three
 travel booking staff proposed to implement the contract demonstrating the required length of
 the work experience mentioned above in 15.1. If Curricula Vitae are submitted, they must bear

- no indication of name or date of birth, only a number. A separate list should be included showing the association between these numbers and actual names.
- In the context of requirements listed in point d) above, Description of services rendered over the course of at least two years, demonstrating how the personal data of at least 30 business travellers have been handled in compliance with Union data protection legislation. Specifically, the description must include:
- technical and organisational measures and internal rules to ensure compliance with storage limitation and data retention requirements (Article 5(1)(e) GDPR) and to ensure compliance with onward transfers to third countries (Chapter V GDPR).
- technical and organisational security measures put in place to ensure appropriate security of
 the personal data, including protection against unauthorised or unlawful processing and against
 accidental loss, destruction or damage, in compliance with Articles 5(1)(f) and 32 GDPR
 ('security of processing'). Measures should be also demonstrated that ensure that persons
 authorised to process the personal data have committed themselves to confidentiality or are
 under an appropriate statutory obligation of confidentiality.
- established process put in place for the handling of personal data breaches to ensure compliance with Articles 33 and 34 GDPR, where the delay mentioned in Article 33.2 shall not be later than 48 hours.
- Please also provide the duly filled-in Annex XIV to the present technical specifications
 ('Standard Contractual Clauses between controllers and processors under Article 28(7) GDPR
 and Article 29(7) of Regulation (EU) 2018/1725'); specifically, tenderers are required to fill-in
 fully annexes I to IV which are incorporated at the end of Annex IX;

17. Award criteria

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

Qualitative award criteria: 50%

Price: 50%

Total 100%

For joint tenders the award criteria shall be evaluated in relation to the tender submitted as a whole, including all consortium members and subcontractors.

17.1. Qualitative award criteria

The qualitative criteria which will apply to this tender are set out in tabular format below including the available points and minimum scores. Any tenderer not achieving the minimum scores indicated below will be eliminated and not evaluated for price. The qualitative award criteria shall account for **50% of the weighting** for this tender.

No.	Qualitative award criterion	Weighting	Maximum points available	Minimum points, which must be achieved
A	Provide an overview of the proposed Online Booking Tool and in particular, please indicate how you are going to ensure that online bookings are made in accordance with EMA reimbursement rules.	30	30	15
	Please ensure that all the following points are addressed in your response: the available level of the OBT customisation; support offered to users; the structure of the team processing the online bookings (CVs should not be provided in response to these criteria); the back-up solutions and support in event of technical problems.			
	Please provide a link to a trial version of the proposed OBT, so the ease of navigation and the user friendliness of the tool can be assessed by the evaluation committee. Please note that the OBT must be web based4.			
	Word limit: max ten A4 pages (Screen shots of the OBT can be appended and will not be included in word count)			
В	Provide an overview of how the offline bookings (i.e. made by email/phone outside of OBT) will be processed and how visa provisions will be organised.	5	5	2.5
	Please also indicate how the team dealing with the offline bookings is going to be organised and what will be the emergency out of hours service offered.			
	Word limit: max four A4 pages			
С	Provide information on how you would ensure a minimum daily availability of 90 hotel nights with hotels located in the immediate vicinity of EMA headquarter respecting the hotel ceilings stated in the Delegates reimbursement rules (Annex VIII)	15	15	7.5
	Please also indicate how you will guarantee that the Agency has access to the lowest prices and fares at all times.			
	Please note that indicative 90 hotel nights is used here only for the purpose of evaluation. It does represent a relatively busy day in terms of meetings at EMA but			

⁴ If the OBT is (or will become) available as an application, which can be downloaded and installed on the mobile devices, the Agency will consider using such application in the future (providing it is approved by the EMA Information Security Office) but only a web-based version of OBT will be tested and assessed by the committee while evaluating the tenders.

No.	Qualitative award criterion	Weighting	Maximum points available	Minimum points, which must be achieved
	does not represent an average daily hotel requirement (as that fluctuates considerably throughout the year and during the week.) Word limit: max five A4 pages			
	TOTAL	50%	50	30

In order to evaluate the above qualitative award criteria, the tenderer must provide answer to each of the criterions (A, B and C) adhering to the page limits indicated.

Marks are awarded for clear and concise answers, with the applicable examples and detail where relevant. The Agency does not wish to receive long and unstructured answers and each criterion states a maximum answer length allowed. Please note that any content, which exceeds the page limit in respect of each question, will not be scored and will be disregarded when evaluating the tender response. Appendices, charts, diagrams or screenshots may be included but count towards the total word limit (unless stated otherwise).

The tenderers should also note that evaluation committee will not consider any references to external sources/hyperlinks (other than the link to the trial version of OBT requested for the criterion A).

17.2. Price

Only those tenderers which have obtained the stipulated minimum score (i.e. 50% for each individual qualitative award criterion and at the same time 60% of the overall points available for all qualitative criteria) shall be evaluated for price and thus for award of the contract.

Price shall account for 50% of the weighting for this procurement procedure.

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

Lowest price x weighting for price (50)
Tenderer's price

For the purposes of evaluation "price" in this formula shall be the "GRAND TOTAL per year" of the scenario in the costing sheet in the costing sheet in **Annex II** calculated to two decimal places.

This scenario is indicative only for the purposes of evaluation and is not binding on the Agency as a future purchase but uses prices which shall be those charged by the tenderer if a contract is awarded.

Tenderers' attention is drawn to Article 23 of Annex I to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, concerning abnormally low tenders.

17.3. Total points for award criteria and ranking

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.

Tenders shall be ranked according to the best price-quality ratio in accordance with the following formula:

Score for tender X = (total points for price awarded to tender X, calculated according to section 17.2 above) + (total quality score tender <math>X / 100)*(50 for quality)

Should the outcome of the formula lead to two or more tenders with the same result, the tenderer who has been awarded the highest marks for quality will be deemed to be the most economically advantageous tender. This approach will continue to be applied to each of the award criteria in the descending order listed below until a most economically advantageous tender can be determined:

The contract shall be awarded to the tender ranked first, which complies with the minimum requirements specified in the procurement documents and is submitted by a tenderer having access to procurement, not in an exclusion situation and fulfilling with the selection criteria.

18. Form and content of the tender

Tenders are to be submitted via the eSubmission application according to the instructions laid down in the Invitation to tender letter and the eSubmission Quick Guide.

Tenderers are reminded to prepare and submit the electronic tender in eSubmission early enough to ensure it is received within the deadline specified under Heading IV.2.2 of the contract notice.

The documents to be submitted with the tender in eSubmission are listed in the Appendix to this document.

The following requirements apply to the technical and financial offer to be uploaded in eSubmission:

Technical offer

The technical offer must be submitted as per the instructions provided in Section 17.1 of this document.

Financial offer

A complete financial offer needs to be uploaded. For this purpose the costing sheet in **Annex II** shall be completed and uploaded in eSubmission.

It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the eSubmission field "Total amount" corresponds to the amount indicated in the uploaded costing sheet. In case of discrepancies, only the amount indicated in the costing sheet will be taken into account.

Appendix: List of documents to be submitted with the tender or during the procedure

Description	Sole tenderer	Joint tender		Identified Subcontractor	When and where to submit the	Instructions for uploading applicable)	ons for uploading in eSubmission (if e)				
		Group leader	Member of the group		document?	How to name the file?	Where to upload?				
1. Identification	1. Identification and information about the tenderer										
eSubmission view											
•											
Ways to subm	it	Parties		Tende	er data	Submission report	Submit				
Cover letter on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer	×	×			With the tender in eSubmission	'Cover letter'	In the Group leader's or Sole tenderer's section under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'				
Tenderer information sheet & declaration on tender submission (see Annex I)	X		X	where more than 10% of the contract per subcontractor will be executed by the	With the tender in eSubmission	`Group overview'	In the Group leader's section under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'				

Description	Sole Joint tender tenderer			Identified Subcontractor	When and where to submit the	Instructions for uploading applicable)	in eSubmission (if
		Group leader	Member of the group		document?	How to name the file?	Where to upload?
				subcontractors]			
Declaration on Honour on Exclusion and Selection Criteria (see Annex III)				where more than 10% of the contract per subcontractor will be executed by the subcontractors	With the tender in eSubmission	'Declaration on Honour'	With the concerned entity under 'Parties' →'Identification tenderer' →'Attachments' →'Declaration on Honour'
Minimum technical requirements declaration (see Section 3.2 and Annex IV)					With the tender in eSubmission	'Minimum requirements declaration'	In the Group leader's or Sole tenderer's section under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'
Power of attorney (see Annex V)					With the tender in eSubmission	'Power of attorney'	In the Group leader's section under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'.
List of identified subcontractors (see Annex VI)					With the tender in eSubmission	`List of identified subcontractors'	In the Sole tenderer's or the Group leader's section under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'

Description	Sole tenderer			Identified When and where to Subcontractor submit the	Instructions for uploading in eSubmission (if applicable)		
		Group leader	Member of the group		document?	How to name the file?	Where to upload?
Letter of intent signed by each identified subcontractor					With the tender in eSubmission	'Letter of intent'	With the concerned entity under 'Parties' →'Identification tenderer' →'Attachments' →'Other documents'
Evidence of non- exclusion (see Section 13) Applies to all tenderers (and each partner in the case of joint offers).	X		X		With the tender in eSubmission	`Exclusion evidence'	With the Group leader or the sole tenderer under 'Parties' →'Identification tenderer' →'Attachments' →'Declaration on honour'
Evidence of legal capacity (see Section 14) Applies to all tenderers (and each partner in the case of joint offers). The Agency may request that supporting evidence be provided by subcontractors at any time during the procedure.					With the tender in eSubmission	`Legal capacity'	With the Group leader or the sole tenderer under 'Parties' →'Identification tenderer' →'Attachments' →'Legal capacity'
Evidence of economic and financial capacity (see Section 15)		no contribute t		by the involved te financial and	With the tender in eSubmission	'Balance_sheet_ entity_year" Profit_Loss_Account_entity_ye	With the Group leader or the sole tenderer under 'Parties' →'Identification tenderer' →'Attachments' →'Economic and

Description	Sole tenderer	Joint tender		Identified Subcontractor	When and where to submit the	Instructions for uploading in eSubmission (if applicable)	
		Group leader	Member of the group		document?	How to name the file?	Where to upload?
Evidence of technical and professional capacity (see Section 16)		nents must be Ibmitted as a v members and	whole, includ	ing all group	With the tender in eSubmission	ar" 'Tech_prof_capacity_a)' 'Tech_prof_capacity_b)' 'Tech_prof_capacity_c)'	financial capacity'. With the Group leader or the sole tenderer under 'Parties' →'Identification tenderer' →'Attachments' →'Technical and professional capacity'

Description	Sole	Joint tender		Identified	When and where to	Instructions for uploading in eSubmission	
	tenderer			Subcontractor		applicable)	
		Group leader	Member		document?	How to name the	Where to upload?
			of the			file?	
			group				

Description	Sole tenderer	Joint tender		Identified Subcontractor	When and where to submit the	Instructions for uploading in eSubmission (if applicable)	
		Group leader	Member of the group		document?	How to name the file?	Where to upload?
2. Tender data.		<u>'</u>	1	'	'		
eSubmission view							
		•					
Ways to su	bmit	Parties		Tender	r data	Submission report	Submit
Failure to upload	the following o	documents in eSu	bmission w	ill lead to rejection	of the tender.		
Fechnical offer see Section 17)	×	X			With the tender in eSubmission	`Technical offer'	Under section 'Tender Data' →'Technical offer'
Financial offer (see Section 9 and Annex II)	\boxtimes	×			With the tender in eSubmission	'Financial offer'	Under section 'Tender Data' →'Financial offer'

