EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health security and Vaccination

SENSITIVE*
RELEASABLE TO: Need to know basis

European Commission

Call for tenders SANTE/2020/C3/087 -

for the development, production, priority-purchasing options and supply of COVID-19 Vaccines for EU Member States

(Advance Purchase Agreement)

Negotiated procedure without prior publication

TENDER SPECIFICATIONS

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TABLE OF CONTENTS

1. SCOPE AND DESCRIPTION OF THE PROCUREMENT

1.1. Contracting authority: who is the buyer?

This call for tenders is launched and managed by the European Commission referred to as the Contracting authority for the purposes of this call for tender.

The contract with the winning tenderer ("Contractor") shall be concluded by the European Commission on behalf and in the name of the following EU Member States (hereinafter referred to as "the Contracting authorities"):

Republic of Austria (AT)
Kingdom of Belgium (BE)
Republic of Bulgaria (BG)
Republic of Croatia (HR)
Republic of Cyprus (CY)
Czech Republic (CZ)
Kingdom of Denmark (DK)
Republic of Estonia (EE)
Republic of Finland (FI)
French Republic (FR)
Federal Republic of Germany (DE)
Hellenic Republic (EL)
Hungary (HU)
Ireland (IE)
Italian Republic (IT)
Republic of Latvia (LV)
Republic of Lithuania (LT)
Grand Duchy of Luxembourg (LU)
Republic of Malta (MT)
Kingdom of the Netherlands (NL)
Republic of Poland (PL)
Portuguese Republic (PT)
Romania (RO)
Republic of Slovakia (SK)
Republic of Slovenia (SI)
Kingdom of Spain (ES)
Kingdom of Sweden (SE)

The contract is divided in two parts or stages ("steps"), the first one aims at financing the development of a safe and effective COVID-19 vaccine in exchange of guaranteeing the right to acquire vaccine doses. The second stage is the production and supply by the Contractor of vaccine doses following requests by the Commission or individual orders placed by the participating Member States. In this second stage, the Commission acts as a central purchasing body for the Member States, that is as *intermediary* by awarding a contract that may be used by the Member States.

1.2. Subject: what is this call for tenders about?

The subject of this tender is financing the research, development and manufacturing of a COVID-19 vaccine in accordance with the applicable legislation, and securing the purchase of certain vaccine doses for the participating Member States.

The first stage will include a pre-financing in the form of one or several up-front payments to de-risk essential investments to increase the speed and scale of manufacturing of vaccines and secure rights for the participating Member States to purchase vaccine doses at a specified price and conditions.

The development of an effective and safe COVID-19 vaccine will save many lives, jobs and billions of euros. Conversely, to the normal practice, where vaccine producers make investments in their production capacity only when they are sure of a viable product, given the current situation of global emergency, investments need to be made now in order to ensure that vaccines will be produced at the scale required as early as possible.

This APA is not exclusive, and different tender procedures to secure vaccines may be launched by the Commission.

In the second stage, through EU-level APAs, the participating Member States would secure supplies from vaccine contractors where the vaccines are successful during clinical trials. To this end, it is necessary to conclude a contract aiming at getting record-time results in the research and development of a safe and effective vaccine against COVID-19. In this context, the up-front financing of part of the vaccine manufacturer's costs for vaccine development, clinical trials and preparation of at-scale production capacity, would de-risk essential investments and increase the speed and scale of manufacturing successful vaccines, while providing the European Union with a major advantage to ensure supply of vaccines for EU citizens. Therefore, in order to maximise the chances of having access to one or several successful vaccines, the Commission may launch several tender procedures with several manufacturers of leading vaccine candidates.

This call for tenders is not divided into lots.

1.3. Description: what do we want to buy through this call for tenders?

1.3.1 Detailed characteristics of the purchase and deliverables

The conditions for the up-front financing of research, development and manufacturing of a safe and effective vaccine for COVID-19 and increase of its production capacity in exchange of the right to buy vaccine doses will be negotiated with an individual company with the objective of supplying the participating Member States. They aim at ensuring that in case of success, the successful vaccine manufacturers produce the capacity required for rapid deployment of millions of doses of a safe and effective vaccine in the EU.

The European Commission will conclude the APA with the selected vaccine producer to ensure proper research and development of a rapid vaccine solution, as well as an increase of their production capacities with the aim to benefit immediately from the results. APAs are divided in two different stages or "steps":

I. The **first step (step I) of the APA** consists in the development by the Contractor of a COVID-19 vaccine:

In order to support the manufacturers with the clinical trials and enhance the Contractor's capacity to produce a vaccine, the Contracting authority (the European Commission) will make a pre-financing in the form of an "up-front" payment according to the terms defined in the APA.

In exchange of the amount paid, the Contractor commits to produce, and supply in priority an agreed timeframe vaccine doses if and/or when requested by the Contracting authority or by the participating Member States. In addition, the Contractor might allow using the production capacities funded by the upfront payments made by the Contracting authority by other producers of successful vaccine(s) should its own vaccine candidate prove to be unsuccessful.

II. The **second step (step II)** entails the following:

- If the first step is successful according to the terms and conditions specified above, the Contractor shall deliver the agreed vaccine doses under the terms specified in the agreed contract. Those terms may provide for delivery to the recipient Member States following a request of the Contracting authority or following purchase orders by the recipient Member States themselves.
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1.3.2 Minimum requirements

The subject of this tender is the development and production of a COVID-19 vaccine in accordance with the applicable legislation. As the development phase of the vaccine has not yet been finalized at the moment of the launch of this call for tenders, it is likely that the certain minimum requirements of the product cannot be evaluated before the APA signature. However, the tender shall commit to the following minimum requirements:

a) Technical requirements for vaccine characteristics

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, (OJ L 136, 30.4.2004, p. 1).).

- Pharmaceutical formula: suspension for injection (preferably)
- Injectable (preferably)
- Primary packaging in single doses or multi-dose vials (preferably max 10 doses per vial)
- The minimum requirements regarding the information on the packaging in accordance with the European law (prospect with adverse reactions, etc.)
- Manufacturing in compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.

Compliance with these requirements is mandatory and cannot be subject to any assumptions, limitations, conditions, or reservations on the part of the tenderer. The Contractor will provide evidence of compliance with the applicable minimum requirements to the Contracting authority from the moment the vaccine is ready for production.

b) Regulatory requirements

The Contractor shall demonstrate compliance with all relevant legislation and regulatory requirements and fulfil necessary licencing requirements particular to the supply of vaccines in the European Union.

The Contractor shall hold a marketing authorisation for a COVID-19 vaccine ahead of placing on the EU market. The vaccine shall be manufactured, controlled and distributed in compliance with Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

During the course of the contract, the Contractor enables the Contracting authorities to carry out a GMP/GDP-inspection at all times. The Contractor shall provide full cooperation during these inspections as long as the inspections are related to this tender. The costs of the inspection are for the account of the Contracting authorities, unless the inspection results in proof of default. In the latter case, all costs are for the account of the Contractor.

c) Other requirements that might be used to guide the purchase of the vaccine

[redacted]

[2] Includes both clinical and pre-clinical immunogenicity data

NB: Requirements in Table 1 are only indicatory in case purchase orders are placed before the Contractor receives the EU Marketing authorization (or the necessary authorisation to place the product on the market of one or more Member States). The requirements listed in the table cannot be considered as any replacement of the European Medicines Agency's (EMA) requirements for COVID-19 vaccine assessment and the EU marketing authorization.

1.3.3 Other provisions related to performance of the APA

1.3.3.1 Contact point

The European Commission will designate a contact point for the overall management of the APA. Each participating Member State will designate a contact point for the management of the specific contracts/order forms, if any.

The Contractor will designate a single contact point for the management of the APA and all specific contracts/order forms.

1.3.3.2 Meetings

Monitoring meetings, e.g. contract implementation monitoring meetings and delivery progress monitoring meetings of the APA will be held according to the APA. Authorised senior representatives of the Contractor that have the authority to make decisions regarding the contract shall attend the meeting.

The costs of attendance of its own representatives for those meetings must be born exclusively by the Contractor.

1.3.3.3 Reports

The Contractor will send reports (e.g., contract implementation monitoring reports;

[3] It is a critical aspect but it is understood that data will not be available by end of 2020

periodical updates of the production and delivery; periodical performance and delivery progress monitoring reports; updates on progress made in terms of clinical development of the vaccine; interim and final results of clinical studies of the vaccine; progress on the build-up of manufacturing capacities; updates on progress; challenges and opportunities, updates on establishment of the supply chain, delivery plans for all Member States, other relevant information on the vaccine, any relevant information for the establishment of the vaccination strategies, etc.) to the European Commission in English by electronic mail as defined in the APA.

All costs related to the Contractor's management obligations under the APA must be borne exclusively by the Contractor and included in the financial offer. The European Commission and the participating Member States will not reimburse any expenses incurred in relation to these tasks and obligations.

1.3.3.4 Quality control

The Contractor must have a comprehensively designed and implemented system for the investigation and documentation of any quality issue in line with Chapters 6 (Quality Control) and Chapter 8 (Complaints, Quality defects and Product Recalls) of the EU Good Manufacturing Practices.

Any quality issue detected by, reported to and/or recorded by the Contractor that might eventually affect the quality and/or supply of the product, shall be reported to the Contracting authority within 7 calendar days. To follow-up, the Contractor shall communicate to the Contracting authority a documented proof that the reported quality issues have been processed and completed according to relevant national legislation.

1.3.3.5 Document and change management

The Contractor must have a document management process and procedures related to this contract. Records are retained according to regulatory requirements, including release, reference samples, and shipping documentation. The Contracting authority [or the participating Member State should the APA contain a right and not an obligation of the participating Member States to acquire the vaccines] retains shipping documentation at the disposal of the competent authorities.

The Contractor must have a management system for follow-up, review, implementation and evaluation of changes related to this contract.

1.3.3.6 Inspections and audits

During the duration of the contract, the Contracting authority [or the participating Member State in accordance with the APA or specific contracts/order forms] reserves a right to carry out inspections, audits or to request from the Contractor any document demonstrating that the latter meets any contractual requirement as defined in the APA.

1.3.3.7 Working languages

All the communication and documents related to carrying out this contract are in English, unless mutually agreed differently by the parties.

1.4. Place of performance: where will the contract be performed?

The research, development and production will be performed in the Contractor's premises (unless outsourced). Once a suitable vaccine has been developed, vaccine doses will be delivered to the locations indicated by the Commission, in accordance with the provisions of the APA, or indicated by the participating Member States in the relevant specific contracts/order forms signed by them. The signature of a specific contract/order form entails the acceptance of the APA terms.

1.5. Nature of the contract: how will the contract be implemented?

The contract (APA) is divided in two parts or stages ("steps"), the first one aims at financing the development and manufacturing of a safe and effective vaccine in exchange of the right to acquire vaccine doses. The second step covers the production and delivery of the vaccine doses to the place of delivery indicated by the Commission or/and the purchase of the vaccines via individual orders placed by the participating Member States.

The signature of an APA does not necessarily impose an obligation on the Contracting authority or the participating Member States to conclude specific contracts/vaccine order forms with an APA Contractor.

The APA is to be concluded with the vaccine manufacturer. The selected manufacturer must a) not be in an exclusion situation, (b) satisfy the selection and award criteria, and (c) submit a tender that complies with the tender specifications.

1.6. Volume and value of the contract: how much do we plan to buy?

A desired number of vaccine doses is indicated in the financial offer (**Annex 6**). Tenderers will indicate the proposed number of vaccine doses in the financial offer. Yet, the final estimated volume number of a vaccine doses for the whole duration of the APA can be further negotiated and included in the APA accordingly.

Should the vaccine be successful, the Contractor will make available the minimum number of vaccine doses agreed within the agreed timeline and price. For APAs containing an obligation of participating Member States to acquire vaccines, the Commission or the participating Member States will indicate to the Contractor the volume per participating Member State and the place of delivery in the conditions laid down in the APA. For APAs containing a right and not an obligation of the participating Member States to acquire the vaccines, the participating Member States will order through specific contracts/order forms on the basis of a population distribution key and their needs.

The APA ceiling shall be determined by the total amount of the successful tenderer's financial offer for the overall estimated volume of upfront costs and purchases, corresponding to the maximum duration of the APA, possibly increased by a reserve of 10% to cover unforeseen

needs of the Contracting authorities.

1.7. Duration of the contract: how long do we plan to use the contract?

The APA(s) for guaranteeing the right of participating Member States to purchase vaccine doses against the coverage of part of the vaccine manufacturer's upfront costs and the subsequent supplies of vaccine doses, resulting from the award of this call for tenders will be [redacted].

[redacted]

1.8. Electronic exchange system: can exchanges under the contract be automated?

For all exchanges with the Contractor during the implementation of the contract as well as for future possible subsequent proceedings for the purposes of EDES (European Union's Early Detection and Exclusion System) the Contracting authority may use an electronic exchange system meeting the requirements of Article 148 of 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. At the request of the Contracting authority the use of such a system shall become mandatory for the Contractor(s) at no additional cost for the Contracting authority. Details on specifications, access, terms and conditions of use will be provided in advance.

2. GENERAL INFORMATION ON TENDERING

2.1. Legal basis: what are the rules?

This call for tenders is governed by the provisions of 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 (the Financial Regulation)[4] and Council Regulation (EU) 2016/369 on the provision of emergency support within the Union[5], as amended by Council Regulation (EU) 2020/521[6] (Article 4(5)(b) in particular). With the purpose of launching this call for tenders, an agreement was concluded between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States. This agreement was approved by Commission Decision C(2020) 4192 final of 18 June 2020 (see Annex 7).

The Contracting authority has chosen to award the contract resulting from this call for tenders through a negotiated procedure without prior publication of a contract notice pursuant to Article 164(1)(d) and (4) of the Financial Regulation and point 11.1(c) of Annex I to the Financial Regulation.

The Contracting authority may negotiate the tenders in order to improve their content or to adapt them to the requirements set out in the procurement documents. The negotiation process is described further in section 3.4.

2.2. Rules on access to procurement: who may submit a tender?

Participation in this call for tenders is open on equal terms to all legal persons which have been invited to submit a tender as follows:

- Legal persons coming within the scope of the Treaties;
- Legal persons established in a third country, which has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement. Where the Agreement on Government Procurement[7] concluded within the World Trade Organisation applies, the participation to this call for tenders is open to all legal persons established in the countries that have ratified this Agreement, on the conditions laid down therein.

The rules on access to procurement do not apply to subcontractors. Subcontracting may not be used with the intent to circumvent the rules on access to procurement.

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4 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, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193 of 30.07.2018, p.1).

5 OJ L 70, 16.3.2016, p. 1.

6 Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, OJ L 117, 15.4.2020, p. 3.

7 https://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm.

To enable the Contracting authority to verify the access, each tenderer must indicate its country of establishment (and in case of joint tender – the country of establishment of each group member) and must present the supporting evidence normally acceptable under the law of that country/-ies. The same document(s) could be used to prove country/-ies of establishment and the delegation(s) of the authorisation to sign as described in **Section 4.3**.

☝ For tenderers established in the United Kingdom:

Please be aware that following the entry into force of the EU-UK Withdrawal Agreement* on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union are to be understood as including natural or legal persons residing or established in the United Kingdom. UK entities, which have been invited to submit a tender, are therefore eligible to participate under this call. * Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.

2.3. Ways to submit a tender: how can economic operators organise themselves to submit a tender?

Only economic operators invited can submit a tender. In principle, only invited economic operators may submit a tender. However, an invited economic operator may form a joint tender with other economic operators (including economic operators who were invited and/or economic operators who were not directly invited). In this case, the tender may be submitted by the leader of the consortium in accordance with **Section 2.4.1**.

In order to fulfil the selection criteria set out in **Section 3.2**, the tenderer can rely on the capacities of subcontractors or other entities (not subcontractors).

The role of each entity involved in a tender (hereafter referred to as involved entity) must be clearly specified: sole tenderer, member of a group or Group leader, subcontractor or an entity on whose capacities the tenderer relies to fulfil the selection criteria[8]. This applies also where the involved entities belong to the same economic group.

2.3.1. Joint tenders

A joint tender is a tender, which 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 tenderer[9].

All members of the group assume joint and several liability towards the Contracting authority and the participating Member States for the performance of the contract as a whole.

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8 Such an entity is not considered a subcontractor, see Section 2.4.3.

9 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.

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 APA signature. The model power of attorney attached in **Annex 3** 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 Contracting authority's contact point for the APA'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 APA execution. If the joint tender is successful, the Contracting authority shall sign the APA with the Group leader, authorised by the other members to sign the APA on their behalf via power of attorney drawn up in the model attached in **Annex 3**.

Changes in the composition of the group during the procurement procedure (after the submission deadline and before the APA signature) shall lead to rejection of the tender except in case of a merger or takeover of a member of the group (universal succession), provided that the new entity has access to procurement (see **Section 2.2**) and is not in an exclusion situation, (see **Section 3.1**).

In any case the selection criteria must be still fulfilled by the group and the terms of the originally submitted tender may not be altered substantially, i.e. all the tasks assigned to the former entity must be taken over by the new entity member of the group, the change must not make the tender non-compliant with the Tender specifications, and the evaluation of award criteria of the originally submitted tender may not be modified.

2.3.2. 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 Contracting authority 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 tender (see **Section 1.3**).
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 procurement documents 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.

By filling in the form available in **Annex 4**, tenderers are required to give an indication of the proportion of the contract that they intend to subcontract, as well as to identify and describe briefly the envisaged contractual roles/tasks of subcontractors meeting any of these conditions (hereafter referred to as identified subcontractors):

- on whose capacities the tenderer relies upon to fulfil the selection criteria as described under **Section 3.2**;
- whose individual share of the contract, known at the time of submission, is above 10 % .

Any such subcontractor must provide the tenderer with a commitment letter drawn up in the model attached in **Annex 5.1** and signed by its authorised representative.

Changes concerning subcontractors identified in the tender (withdrawal/replacement of a subcontractor, additional subcontracting) during the procurement procedure (after the submission deadline and before the APA signature) require the prior written approval of the Contracting authority subject to the following verifications:

- any new subcontractor is not in an exclusion situation;
- the tenderer still fulfils the selection criteria and the new subcontractor fulfils the selection criteria applicable to it individually, if any;
- the terms of the originally submitted tender are not altered substantially, i.e. all the tasks assigned to the former subcontractor are taken over by another involved entity, the change does not make the tender non-compliant with the Tender specifications, and the evaluation of award criteria of the originally submitted tender is not modified.

Subcontracting to subcontractors identified in a tender that was accepted by the Contracting authority and resulted in a signed APA, is considered authorised.

2.3.3. Entities on whose capacities the tenderer relies to fulfil the selection criteria

In order to fulfil the selection criteria a tenderer may also rely on the capacities of other entities, regardless of the legal nature of the links it has with them. It must in that case prove that it will have at its disposal the resources necessary for the performance of the APA by producing a commitment letter in the model attached in **Annex 5.2,** signed by the authorised representative of such an entity, and the supporting evidence that those other entities have the respective resources.

If the APA is awarded to a tenderer intending to rely on another entity to meet the minimum levels of economic and financial capacity, the Contracting authority may require the entity to sign the APA or, alternatively, to provide a joint and several first-call financial guarantee for the performance of the APA.

With regard to technical and professional selection criteria, a tenderer may only rely on the capacities of other entities where the latter will perform the works or services for which these capacities are required (i.e. the latter will assume the role of subcontractors).

☝ Relying on the capacities of other entities is only necessary when the capacity of the tenderer is not sufficient to fulfil the required minimum levels of capacity. Abstract commitments that other entities will put resources at the disposal of the tenderer will be disregarded.

3. 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 2.2**);
- Verification of administrative compliance (if the tender is drawn up in one of the official EU languages and signed by duly authorised representative(-s) of the tenderer);
- Verification of non-exclusion of tenderers on the basis of the exclusion criteria set out in the Financial Regulation;
- Selection of tenderers on the basis of selection criteria;
- Verification of compliance with the minimum requirements defined in the Tender specifications;
- Evaluation of tenders on the basis of the award criteria.

The Contracting authority 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 APA.

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 Contracting authority during the procedure. If any of the declarations or information provided proves to be false, the Contracting authority 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 Contracting authority may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

3.1. 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 the Financial Regulation.

As evidence of non-exclusion the tenderer needs to submit with its tender a Declaration on Honour[10] in the model available in **Annex 2**.[11] The declaration must be signed by an authorised representative of the entity providing the declaration.

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[10] The European Single Procurement Document (ESPD) may not be used yet in European Commission's calls for tenders.

[11] Unless the same declaration has already been submitted for the purposes of another award procedure of the European Commission, the situation has not changed, and the time elapsed since the issuing date of the declaration does not exceed one year.

The initial verification of non-exclusion of tenderers will be done on the basis of the submitted declarations and consultation of the European Union's Early Detection and Exclusion System (EDES). 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 the Contracting authority[12].

Annex 1 specifies which of the involved entities participating in a tender need to provide the Declaration on Honour and, when requested by the Contracting authority, the supporting evidence.

Please note that a request for evidence in no way implies that the tenderer has been successful.

3.2. Selection criteria

The objective of the selection criteria is to assess whether the tenderer has the legal, regulatory, economic, financial, technical and professional capacity to perform the APA.

The selection criteria for this call for tenders, including the minimum levels of capacity, the basis for assessment and the evidence required, are specified in the following subsections.

The tender submitted by the tenderer not meeting the minimum levels of capacity will be rejected.

When submitting its tender the tenderer shall declare on honour that it fulfils the selection criteria for the call for tender. The model Declaration on Honour available in **Annex 2** shall be used.

The initial assessment of whether a tenderer fulfils the selection criteria will be done on the basis of the submitted declaration(s).

The subsections below specify for which selection criteria evidence must be provided with the tender or may be requested later, at any time during the procurement procedure[13]. In any case,

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12 The obligation to provide the supporting evidence will be waived in the following situations:

- if the same documents have already been provided in a previous award procedure of the European Commission, have been issued no more than one year before the date of their request by the *Contracting authority* and are still valid at that date;
- if such evidence can be accessed by the *Contracting Authority* on a national database free of charge, in which case the economic operator shall provide *the Contracting authority* with the internet address of the database and, if needed, the necessary identification data to retrieve the document;
- if there is a material impossibility to provide such evidence.

13 The obligation to provide the supporting evidence will be waived in the following situations:

- if the same documents have already been provided in a previous award procedure of the European Commission, have been issued no more than one year before the date of their request by the *Contracting authority* and are still valid at that date;

to the extent that there is no ground for a waiver, the evidence must be provided, upon request and within a deadline given by the Contracting authority. The evidence must be provided in accordance with the applicable basis for assessment of each criterion: in case of a consolidated assessment – only by the involved entities who contribute to the fulfilment of the criterion, and in case of individual assessment – by each involved entity to whom the criterion applies individually.

3.2.1. Legal and regulatory capacity

Tenderers must have legal capacity to perform the contract and the regulatory capacity to pursue the professional activity necessary to carry out the work subject to this call for tenders, namely:

- The economic operator must be constituted and/or registered in accordance with the law of the country in which it is established (e.g. trade register).
- The business activity of the economic operator must be related to the subject of the contract (depending on its contribution in the performance of the contract).
- The economic operator must be compliant with all relevant legislation and regulatory requirements and fulfil necessary licencing requirements particular to vaccine research and clinical trials.

This criterion applies to the tenderer as a whole (including all subcontractors and third parties on which the tenderer relies to fulfil some selection criteria).

The legal and regulatory capacity shall be proven by the evidence listed below:

- Proof of enrolment in a relevant trade or professional register clearly stating the tenderer's exact name, business activity and that the tenderer is authorised to perform the contract in its country of establishment.
- A valid or a pending authorisation for vaccine research and clinical trials.
- Any other document(s) proving the compliance with the criterion.

☝ The above specified evidence of legal and regulatory capacity must be provided with the tender.

3.2.2. Economic and financial capacity

The tenderer must comply with the following selection criteria in order to prove that it has the necessary economic and financial capacity to perform the APA.

Criterion F1	
Description	The tenderer must prove to be financially viable to fulfil its

-if such evidence can be accessed by the *Contracting Authority* on a national database free of charge, in which case the economic operator shall provide the *Contracting authority* with the internet address of the database and, if needed, the necessary identification data to retrieve the document.

	obligations under the APA during the project development phase of the next twelve months. Financial viability of the tenderer will be checked by calculating a survival ratio as per explanations below.
Minimum level of capacity	
Basis for assessment	This criterion applies to the tenderer. It will be checked for all involved entities (sole tenderer, group members in case of a joint tender, including subcontractors or third parties involved).
Evidence	

Explanation of the ratio:

The survival ratio will be calculated as follows:

If the survival ratio calculated on this basis is 1 or higher, the financial and economic capacity of the tenderer will be evaluated as proven.

The evidence of economic and financial capacity does not need to be provided with the tender but may be requested by the EU Validation Services at any time during the procedure. **Please note that a request for evidence in no way implies that the tenderer has been successful.**

3.2.3. Technical and professional capacity

Tenderers must comply with the following selection criteria in order to prove that they have the necessary technical and professional capacity to perform the APA.

Criterion T1
The tenderer must prove to meet high quality and safety standards while manufacturing

Criterion T1	
medicinal products for human use.	
Minimum level of capacity	The tenderer must have implemented, within the company, Good manufacturing practice (hereafter, GMP)[1] or GMP equivalent standards in its production processes.
Basis for assessment	This criterion applies to the tenderer (in case of a joint tender, at least one member of the group) or declared subcontractor, which will manufacture supplies subject of this call for tender.
Evidence	– Copy of a valid EU GMP certificate issued by a competent authority; or failing that, – Confirmation by an authorised body of the country where production takes place that it conforms to GMP standards equivalent to those in the EU.

Criterion T2	
The tenderer must prove to be able to provide high quality services while performing activities of this call for tender.	
Minimum level of capacity	The tenderer must have implemented, within the company, a Quality Management System, based on ISO 9001 or equivalent, in respect of the activities subject of this call for tender.
Basis for assessment	This criterion applies to the tenderer (in case of a joint tender, at least one member of the group) or declared subcontractor and third party making technical resources available to the tenderer.
Evidence	– Copy of valid ISO 9001 certificate or equivalent; or, failing that, – Document demonstrating that the tenderer has implemented a Quality Management System for the services within its company based on ISO 9001 or

[1] In compliance with:

- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262 of 14.10.2003, p. 22-26).
- Commission guidelines of 5 November 2013 on good distribution practice of medicinal products for human use (OJ C 343 of 23.11.2013, p. 1-14).
- Commission guidelines of 19 March 2015 on principles of good distribution practice of active substances for medicinal products for human use (OJ C 95 of 21.3.2015, p. 1-9).
- Commission guidelines of 19 March 2015 on the formalized risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (OJ C 95 of 21.3.2015, p. 10-13).

Further information on GMP can be found on: https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice

Criterion T2	
	equivalent.

Criterion T3	
The tenderer must prove that one of its activities is related to the development and/or manufacturing of COVID-19 vaccine.	
Minimum level of capacity	The tenderer must have an activity related to the development of a COVID-19 vaccine.
Basis for assessment	This criterion applies to the tenderer (in case of a joint tender, at least one member of the group) or declared subcontractor or third party making technical resources available to the tenderer.
Evidence	– Notification or a study description or any other document proving the preparation of, contribution to or initiation of clinical trials; or, failing that, – Confirmation by an authorised body of the country where the activity takes place; or, failing that, – Document demonstrating that the tenderer has an activity related to the development and/or manufacturing of such product supported by a valid documentary evidence. COVID-19 vaccine.

☝ The evidence of technical and professional capacity needs to be provided with the tender but may be requested by the Contracting authority at any time during the procedure. **Please note that a request for evidence in no way implies that the tenderer has been successful.**

☝ Involved entities must not be subject to conflicting interests, which may negatively affect the contract performance. Where the Contracting authority has established such conflicting interests, it may conclude that the tenderer or an involved entity does not possess the required professional capacity to perform the APA to an appropriate quality standard.

The presence of conflicting interests shall be examined during the evaluation phase based on the statements made through the Declarations on Honour and, where applicable, the commitment letters (**Annex 5.1 and Annex 5.2**).

3.3. Compliance with the minimum requirements of the Tender specifications

By submitting a tender, a tenderer commits to perform the contract(s) in full compliance with the terms and conditions of the procurement documents for this call for tender. Particular attention is drawn to the fact that tenders must comply with applicable data protection, 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.

3.4. Negotiation

In accordance with **Section 2.1** of the tender specifications**,** tenders can be negotiated.

The tenderer shall submit its first offer within the deadline indicated in the Invitation to tender. Details concerning the submission of the tenders are provided in the Invitation to tender.

The Commission may negotiate the offer submitted (as well as any successive offer) with the tenderer, in order to adapt it to the procurement documents and/or to find the best commercial offer.

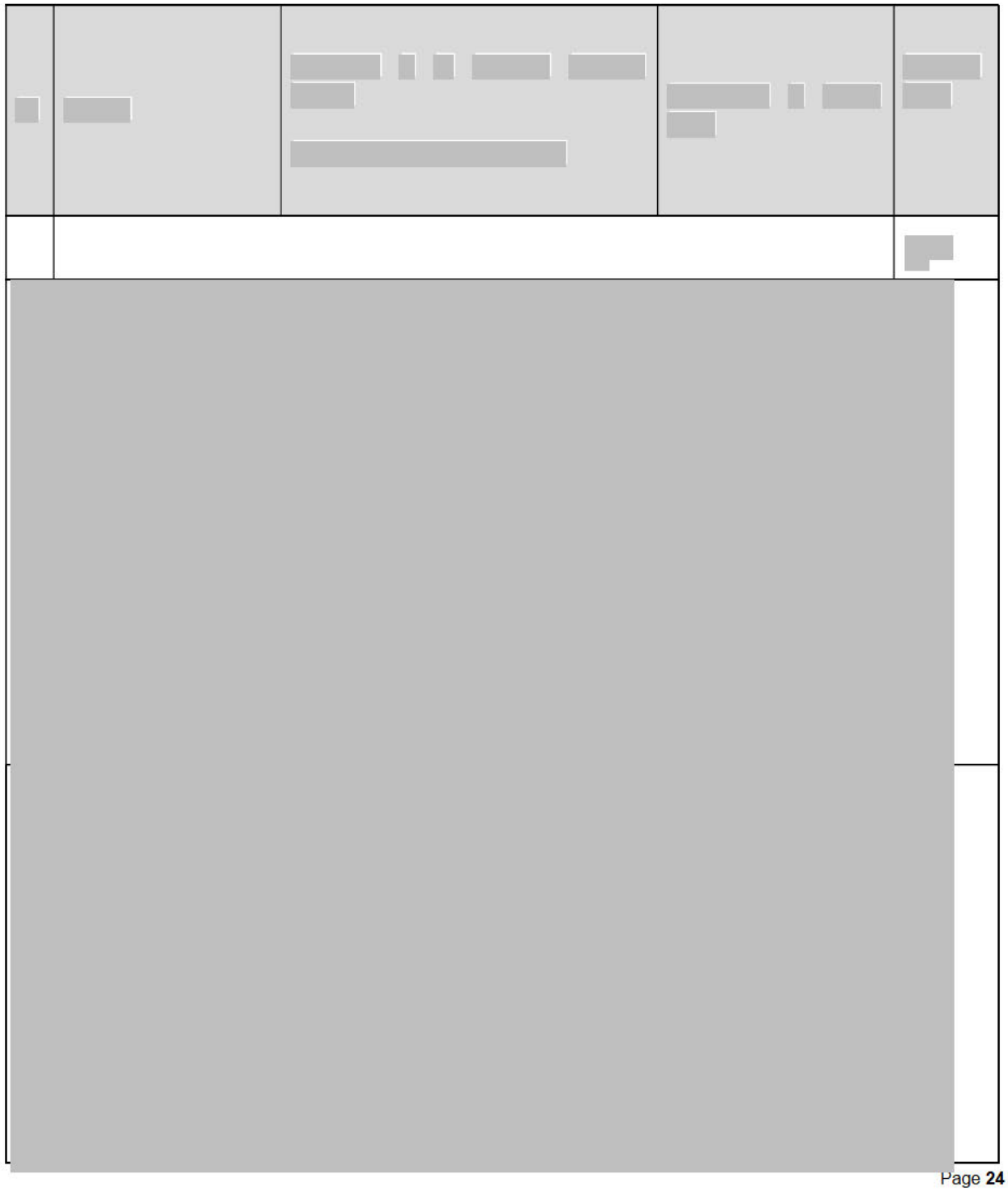
Negotiations will be conducted in an iterative way, based on the successive tenders submitted for each negotiation round. The Commission also reserves the right to award a contract on the basis of the initial tender without negotiation.

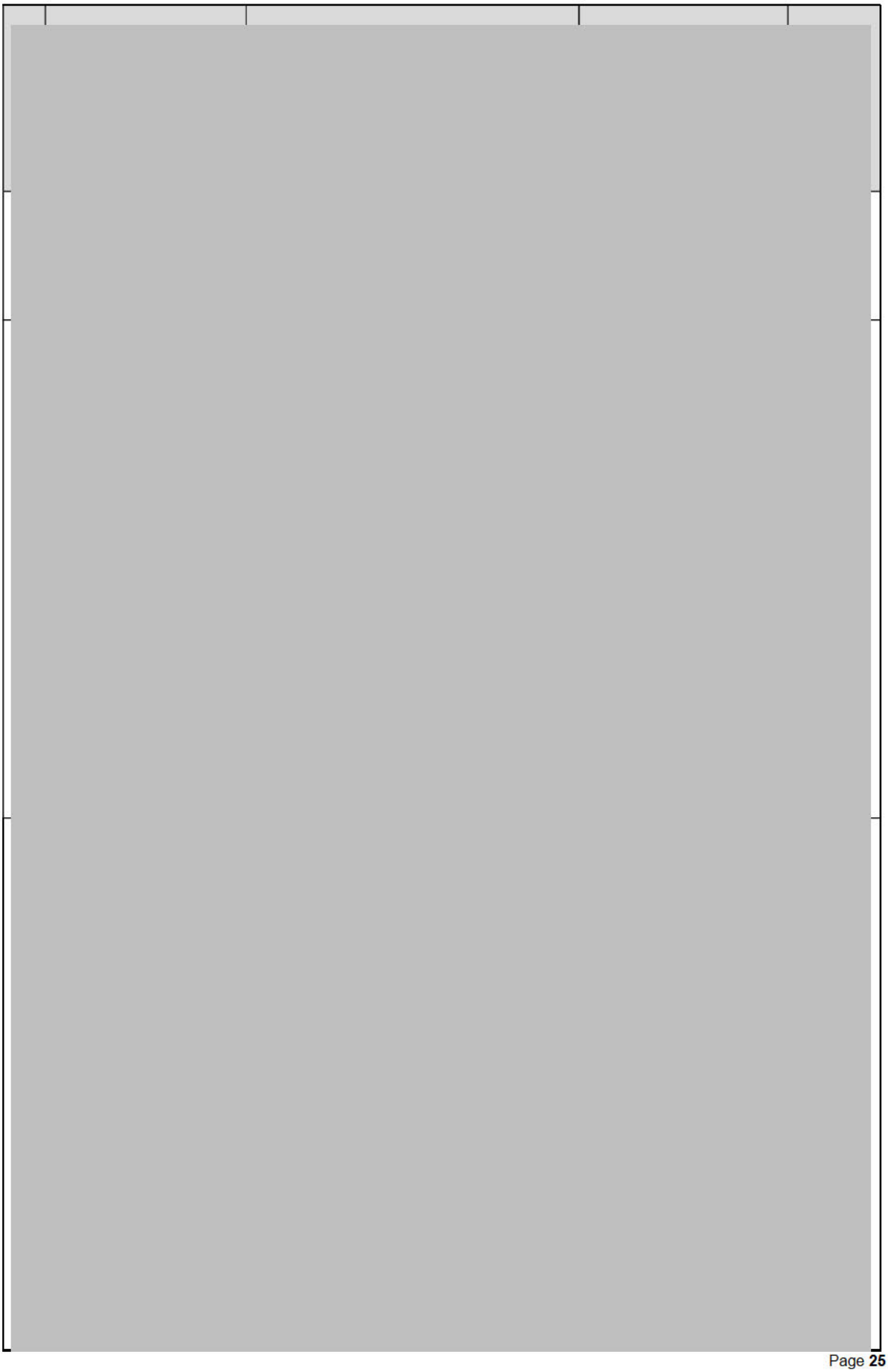
The negotiation may not modify the minimum requirements nor the exclusion, selection and award criteria specified in the procurement documents. A contrario, negotiations may address the technical and financial conditions of the tender as well as non-substantial aspects of the conditions of the contract.

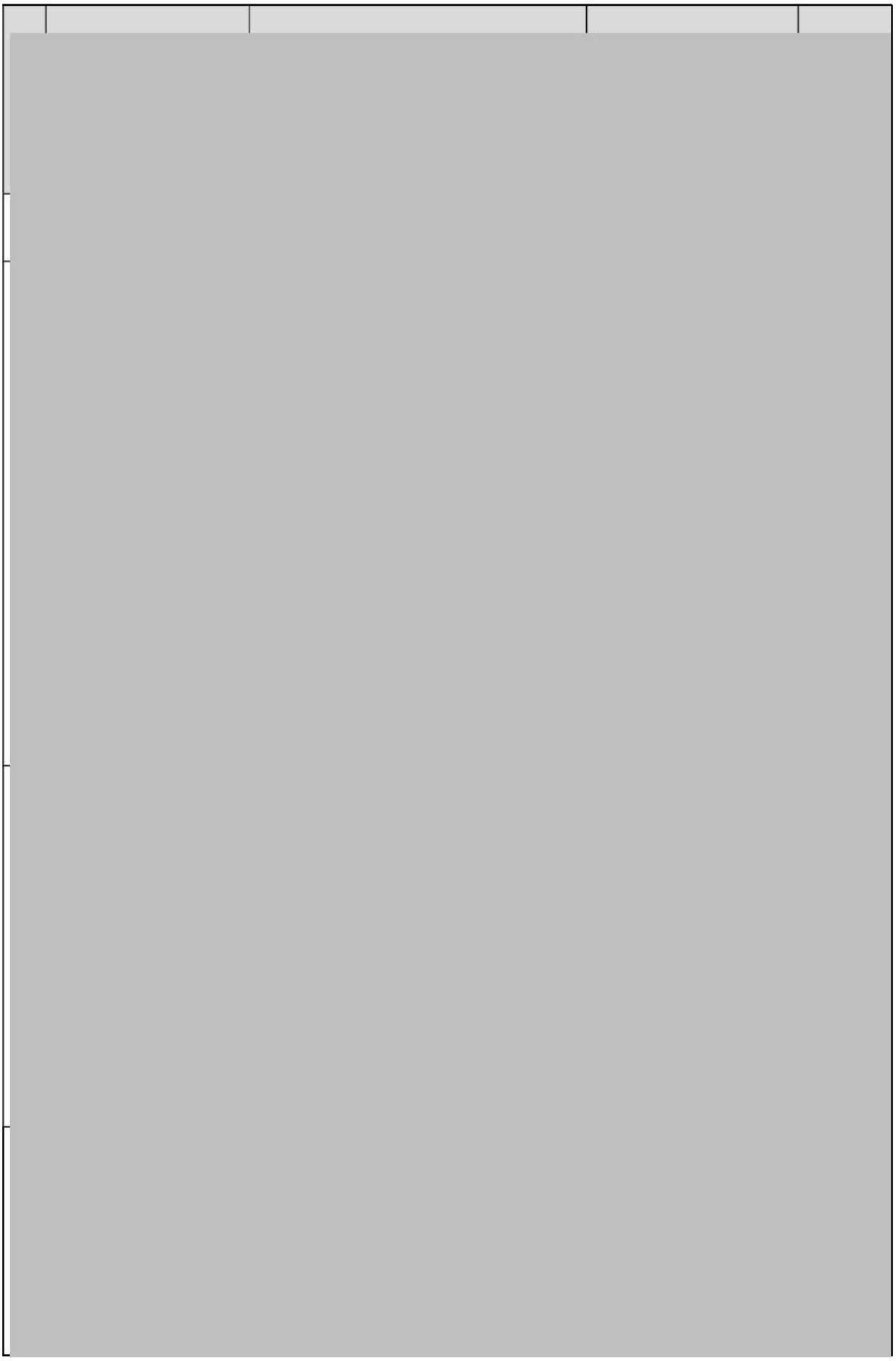
3.5. Award criteria

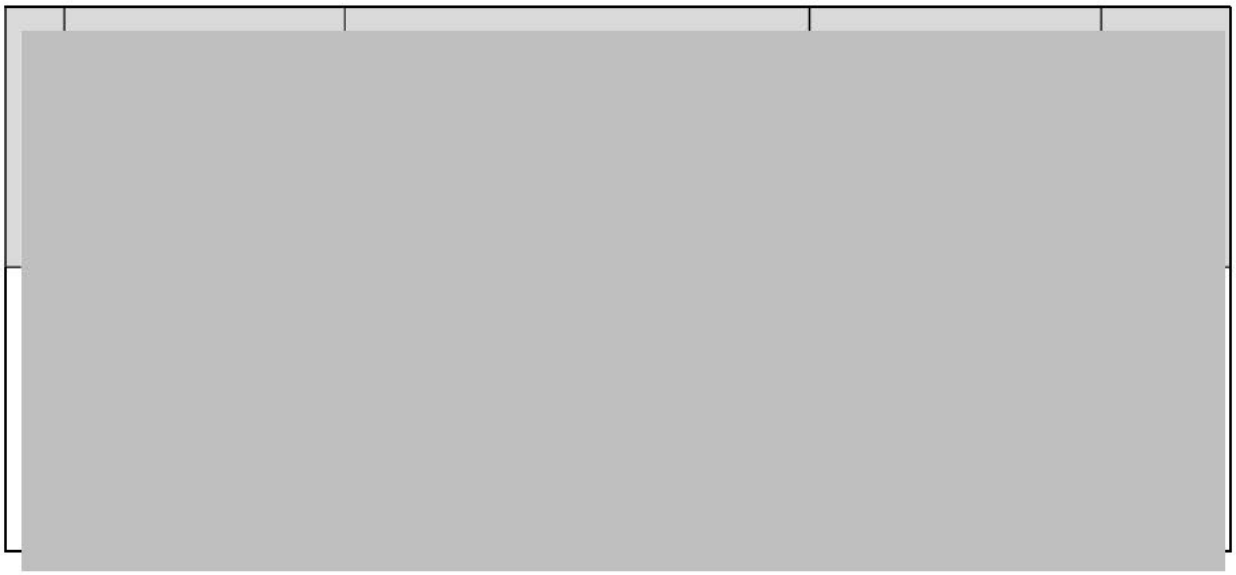
The objective of the award criteria is to evaluate the tenders with a view to choosing the most economically advantageous tender.

Tenders will be evaluated on the basis of the following award criteria:









4. FORM AND CONTENT OF THE TENDER

4.1. Form of the tender: how to submit the tender?

Tenders are to be submitted according to the instructions laid down in the Invitation to tender letter.

☝ Make sure you prepare and submit your tender early enough to ensure it is received within the deadline specified under point 1 of the Invitation to tender. A tender received after this deadline will be rejected.

4.2. Content of the tender: what documents to submit with the tender?

The documents to be submitted with the tender are listed in **Annex 1.**

The following requirements apply to the technical and financial offer:

- Technical offer.

The technical offer must provide all the information needed to assess the compliance with the exclusion, selection and award criteria, including the supporting evidence listed in **Annex 1**.

- Financial offer.

A complete financial offer, including the breakdown of the price needs to be submitted. For this purpose, the Financial Model in **Annex 6** shall be completed electronically, following the instructions in the price schedule and duly signed.

The financial offer shall be:

- expressed in euros. Preferably, tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- quoted free of all duties, taxes and other charges, i.e. also free of VAT. The tenderer must indicate the amount of VAT but it must be shown separately.
- all units in the price schedule must be completed. No fields may be left blank. If the price of a service is EUR 0, tenderers must indicate it in that way (no symbols: -, /, etc.).

☝ The European Union Institutions are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 annexed to the Treaty on the Functioning of the European Union. Exemption is granted to the Commission by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption.

For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT must be shown separately. In case of doubt about the

applicable VAT system, it is the tenderer's responsibility to contact his or her national authorities to clarify the way in which the European Union is exempt from VAT.

The tenders can be negotiated in accordance with section 2.1 of the tender specifications.

4.3. Signature policy: how can documents be signed?

Where a document needs to be signed, the signature must be either hand-written, a qualified electronic signature or an advanced electronic signature based on a qualified certificate as defined in Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (the eIDAS Regulation).

For hand-written signatures see Section 1 of the Invitation to tender.

All documents must be signed by the duly authorised representatives.

For the following documents, when signed by representatives, tenderers must provide evidence for the delegation of the authorisation to sign:

- The Declaration on Honour of the tenderer (in case of joint tender – the Declarations on Honour of all group members) attached in **Annex 2**;
- The **price schedule** in PDF format attached in **Annex 6**;
- If applicable:
    - in the case of joint tender, the power(s) of attorney drawn up using the model attached in **Annex 3**;
    - in case of subcontracting, the **Commitment letter(s) by identified subcontractor** (s) attached in **Annex 5.1**;
    - in case of a third party making economic and financial and/or technical and professional resources available to the tenderer, the **Commitment letter(s) by entity(s) on whose capacities is(are) being relied** attached in **Annex 5.2**.

The delegation of the authorisation to sign on behalf of the signatories (including, in the case of proxy(-ies), the chain of authorisations) must be evidenced by appropriate written evidence (copy of the notice of appointment of the persons authorised to represent the legal entity in signing contracts (together or alone), or a copy of the publication of such appointment if the legislation which applies to signatory requires such publication or a power of attorney). A document that the Contracting authority can access on a national database free of charge does not need to be submitted if the Contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

4.4. Confidentiality of tenders: what information and under what conditions can be disclosed?

Once the Contracting authority has opened a tender, it becomes its property and shall be treated confidentially, subject to the following:

- For the purposes of evaluating the tender and, if applicable, implementing the contract, performing audits, benchmarking, etc., the Contracting authority is entitled to make available (any part of) the tender to its staff and the staff of other Union

institutions, agencies and bodies, as well to other persons and entities working for the Contracting authority or cooperating with it, including Contractors or subcontractors and their staff provided that they are bound by an obligation of confidentiality.

- After the signature of the award decision tenderers whose tenders were received in accordance with the submission modalities, who have access to procurement, who are not found to be in an exclusion situation referred to in Article 136(1) of the FR, who are not rejected under Article 141 of the FR, whose tenders are not found to be incompliant with the procurement documents, and who make a request in writing will be notified of the name of the tenderer to whom the contract is awarded, the characteristics and relative advantages of the successful tender and the price of the offer and/or contract value. The Contracting authority may decide to withhold certain information that it assesses as being confidential, in particular where its release would prejudice the legitimate commercial interests of economic operators or might distort fair competition between them. Such information may include, without being limited to, confidential aspects of tenders such as unit prices included in the financial offer, technical or trade secrets[14].
- The Contracting authority may disclose the submitted tender in the context of a request for public access to documents, or in other cases where the applicable law requires its disclosure. Unless there is an overriding public interest in disclosure[15], the Contracting authority may refuse to provide full access to the submitted tender, redacting the parts (if any) that contain confidential information, the disclosure of which would undermine the protection of commercial interests of the tenderer, including intellectual property.

☝ The Contracting authority will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. The Contracting authority reserves the right to make its own assessment of the confidential nature of any information contained in the tender.

[14] For the definition of trade secrets please see Article 2 (1) of DIRECTIVE (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

[15] See Article 4 (2) of the REGULATION (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

APPENDIX: LIST OF REFERENCES

Award criteria	See Section 3.4
Contracting authority	See Section 1.1
Entities on whose capacities the tenderer relies to fulfil the selection criteria	See Section 2.4.3
EU Validation services	See Section 2.3 EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment
Exclusion criteria	See Section 3.1
Financial Regulation	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
Group leader	See Section 2.4.1
Identified subcontractors	See Section 2.4.2
Involved entities	See Section 2.4
Joint tender	See Section 2.4.1
Participating entities	See Section 1.1
Participant Register	See Section 2.3 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-registerhttps://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant- -
Selection criteria	See Section 3.2
Sole tenderer	See Section 2.4
Subcontracting/subcontractor	See Section 2.4.2
Treaties	The EU Treaties: https://europa.eu/european-union/law/treaties_en

ANNEXES

Annex 1. List of documents to be submitted with the tender or during the procedure[16]

[16] If a tenderer cannot submit the requested evidence with the tender due to circumstances that he/she cannot control, such evidence can be also submitted at a later stage of the procedure, following the Contracting authority's request.

[17] Participant Identification Code: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-an-organisation_en.htm

[18] https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

[19] A document that the Contracting authority can access on a national database free of charge does not need to be submitted, if the Contracting authority is provided with the exact internet link and, if applicable, the necessary identification data to retrieve the document.

[20] Financial capacity assessment: H2020 Financial self-check tool.https://ec.europa.eu/research/participants/lfv/lfvSimulation.do

[21] The documents must be provided only by the involved entities who contribute to reaching the minimum capacity level for criterion F1

[22] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register

[23] The documents must be provided only by the involved entities who contribute to reaching the minimum capacity level for criterion T1

Description	Sole tenderer	Joint tender		Identified Subcontractor	Entity on whose capacity is being relied	When and where to submit the document?
		Group leader	Member of the group			

Description	Sole tenderer	Joint tender		Identified Subcontractor	Entity on whose capacity is being relied	When and where to submit the document?
		Group leader	Member of the group			
[redacted]						
[redacted]	[redacted]					[redacted]

Annex 2. Declaration on Honour on exclusion and selection criteria

Declaration on honour on exclusion criteria and selection criteria

The undersigned [insert name of the signatory of this form], representing:

(only for natural persons) himself or herself	(only for legal persons) the following legal person:
ID or passport number: (‘the person’)	Full official name: Official legal form: Statutory registration number**:** Full official address: VAT registration number: (‘the person’)

The person is not required to submit the declaration on exclusion criteria if the same declaration has already been submitted for the purposes of another award procedure of the same Contracting authority[24], provided the situation has not changed, and that the time that has elapsed since the issuing date of the declaration does not exceed one year.

In this case, the signatory declares that the person has already provided the same declaration on exclusion criteria for a previous procedure and confirms that there has been no change in its situation:

Date of the declaration	**Full reference to previous procedure**

I – Situation of exclusion concerning the person

(1) declares that the above-mentioned person is in one of the following situations:	YES	NO
(a) it is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under Union or national law;	☐	☐

[24] The same EU institution, agency, body or office.

(b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;	☐	☐
(c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibity where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		
(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility or selection criteria or in the performance of a contract or an agreement;	☐	☐
(ii) entering into agreement with other persons with the aim of distorting competition;	☐	☐
(iii) violating intellectual property rights;	☐	☐
(iv) attempting to influence the decision-making process of the Contracting authority during the award procedure;	☐	☐
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	☐	☐
(d) it has been established by a final judgement that the person is guilty of any of the following:		
(i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	☐	☐
(ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in other applicable laws;	☐	☐
(iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;	☐	☐
(iv) money laundering or terrorist financing, within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;	☐	☐
(v) terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	☐	☐
(vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	☐	☐
(e) it has shown significant deficiencies in complying with the main obligations in the performance of a contract or an agreement financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following	☐	☐

checks, audits or investigations by a Contracting authority, the European Anti-Fraud Office (OLAF) or the Court of Auditors;		
(f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	☐	☐
(g) it has been established by a final judgment or final administrative decision that the person has created an entity under a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business.	☐	☐
(h) (only for legal persons) it has been established by a final judgment or final administrative decision that the person has been created with the intent provided for in point (g).	☐	☐
(i) for the situations referred to in points (c) to (h) above the person is subject to: i. facts established in the context of audits or investigations carried out by the European Public Prosecutor's Office after its establishment, the Court of Auditors, the European Anti-Fraud Office (OLAF) or the internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii. non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; iii. facts referred to in decisions of entities or persons being entrusted with EU budget implementation tasks; iv. information transmitted by Member States implementing Union funds; v. decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law; or vi. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.	☐	☐

II – Situations of exclusion concerning natural or legal persons with power of representation, decision-making or control over the legal person and beneficial owners

Not applicable to natural persons, Member States and local authorities

(2) declares that a natural or legal person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers e.g. company directors, members of management or supervisory bodies, and cases where one natural or legal person holds a majority of shares), or a beneficial owner of the person (as referred to in point 6 of article 3 of Directive (EU) No 2015/849) is in one of the following situations:	YES	NO	N/A
Situation (c) above (grave professional misconduct)	☐	☐	☐
Situation (d) above (fraud, corruption or other criminal offence)	☐	☐	☐

Situation (e) above (significant deficiencies in performance of a contract)	☐	☐	☐
Situation (f) above (irregularity)	☐	☐	☐
Situation (g) above (creation of an entity with the intent to circumvent legal obligations)	☐	☐	☐
Situation (h) above (person created with the intent to circumvent legal obligations)	☐	☐	☐
Situation (i) above	☐	☐	☐

III – Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the legal person

(3) declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations:	YES	NO	N/A
Situation (a) above (bankruptcy)	☐	☐	☐
Situation (b) above (breach in payment of taxes or social security contributions)	☐	☐	☐

IV – Grounds for rejection from this procedure

(4) declares that the above-mentioned person:	YES	NO
Was previously involved in the preparation of the procurement documents used in this award procedure, where this entailed a breach of the principle of equality of treatment including distortion of competition that cannot be remedied otherwise.	☐	☐

V – Remedial measures

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines or of any taxes or social security contributions. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

VI – Evidence upon request

Upon request and within the time limit set by the Contracting authority the person must provide 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.

It must also provide the following evidence concerning the person itself and the natural or legal persons on whose capacity the person intends to rely, or a subcontractor and concerning the natural or legal persons which assume unlimited liability for the debts of the person:

For situations described in (a), (c), (d), (f), (g) and (h), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial

or administrative authority in the country of establishment of the person showing that those requirements are satisfied.

For the situation described in point (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another award procedure of the same Contracting authority[25]. The documents must have been issued no more than one year before the date of their request by the Contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	**Full reference to previous procedure**
Insert as many lines as necessary.	

VII – Selection criteria

(1) declares that the above-mentioned person complies with the selection criteria applicable to it individually as provided in the tender specifications:	YES	NO	N/A
(a) It has the legal and regulatory capacity to pursue the professional activity needed for performing the contract as required in section 3.2.1 of the tender specifications;	☐	☐	☐
(b) It fulfills the applicable economic and financial criteria indicated in section 3.2.2 of the tender specifications;	☐	☐	☐
(c) It fulfills the applicable technical and professional criteria indicated in section 3.2.3 of the tender specifications.	☐	☐	☐

(2) if the above-mentioned person is the **sole tenderer** or the **leader in case of joint tender**, declares that:	YES	NO	N/A
(d) the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, complies with all	☐	☐	☐

[25] The same institution or agency.

the selection criteria for which a consolidated asseessment will be made as provided in the tender specifications.			

VIII – Evidence for selection

The signatory declares that the above-mentioned person is able to provide the necessary supporting documents listed in the relevant sections of the tender specifications and which are not available electronically upon request and without delay.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure of the same Contracting authority[26]. The documents must have been issued no more than one year before the date of their request by the Contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	**Full reference to previous procedure**
Insert as many lines as necessary.	

The above-mentioned person must immediately inform the Contracting authority of any changes in the situations as declared.

The above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.

Full name Date Signature

[26] The same institution of agency.

Annex 3. Power of attorney

Call for tenders SANTE/2020/C3/087 - for the development, production, priority-purchasing options and supply of COVID-19 Vaccines for EU Member States

POWER OF ATTORNEY

The undersigned:
– Signatory (Name, Function, Company, Registered address, VAT Number)
having the legal capacity required to act on behalf of his/her company,

HEREBY AGREES TO THE FOLLOWING:

1) To submit a joint tender as a member of a group of tenderers (the Group), constituted by Company 1, Company 2, Company N (Group members), and led by Company 1 (Group leader), in accordance with the conditions specified in the Tender specifications and the terms specified in the tender to which this Power of attorney is attached.
2) If the Contracting authority awards the contract resulting from this call for tenders to the *Group* on the basis of the joint tender to which this power of attorney is attached, all *Group members* shall be considered parties to the contract in accordance with the following conditions:
   (a) All *Group members* shall be jointly and severally liable towards the Contracting authority for the performance of the contract.
   (b) All *Group members* shall comply with the terms and conditions of the contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the contract.
3) Payments by the Contracting authority related to the services and/or supplies subject to the Contract shall be made through the bank account of the *Group leader*: [Provide details on bank, address, account number]. Payment to the *Group leader* discharges the Contracting authority from its payment obligation *vis a vis* other *Group members*.
4) The *Group members* grant to the *Group leader* all the necessary powers to act on their behalf in the submission of the tender and the conclusion of the contract, including:
   (a) The *Group leader* shall submit the tender on behalf of all *Group members* and indicate the name and e-mail address of an individual - single point of contact authorised to communicate officially with the Contracting authority in connection with the submitted tender on behalf of all *Group members,* including in connection with all relevant questions, clarification requests, notifications, etc., that may be received during the evaluation, award and until the contract signature.
   (b) The *Group leader* shall sign any contractual documents — including the contract, and amendments thereto — and issue any invoices related to the performance of the contract on behalf of all *Group members*.
   (c) The *Group leader* shall act as a single contact point with the Contracting authority in the

delivery of the services and/or supplies subject to the contract. It shall co-ordinate the delivery of the services and/or supplies by the *Group* to the Contracting authority, and shall see to a proper administration of the contract.

Any modification to the present Power of attorney shall be subject to the Contracting authority's express approval. This Power of attorney shall expire when all the contractual obligations of the *Group* have ceased to exist. The parties cannot terminate it before that date without the Contracting authority's consent.

Place and date:

Name (in capital letters), function, company and signature:

Annex 4. List of identified subcontractors

Identification details	Roles/tasks during contract execution	Proportion of subcontracting (% of contract volume)
[Full official name Registered address Statutory registration number VAT registration number]		
[Full official name Registered address Statutory registration number VAT registration number]		
[REPEAT AS MANY TIMES AS THE NUMBER OF IDENTIFIED SUBCONTRACTORS]		
Other subcontractors that do not need to be identified under Section 2.4.2		
	TOTAL % of subcontracting	0,00%

Annex 5.1. Commitment letter by an identified subcontractor

[Letterhead, if any]

EUROPEAN COMMISSION

Call for tenders Ref. SANTE/2020/C3/087

Attn:

[Insert date]

Commitment letter by identified subcontractor

I, the undersigned,

Name:

Function:

Company:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of the company **[insert name of the entity]** hereby confirm that our company agrees to participate as subcontractor in the offer of

Done at:

Name:

Position:

Signature:

Annex 5.2. Commitment letter by an entity on whose capacities is being relied

[Letterhead, if any]

EUROPEAN COMMISSION

Call for tenders Ref. SANTE/2020/C3/087

Attn:

[Insert date]

Commitment letter by an entity on whose capacity is being relied

I, the undersigned,

Name:

Function:

Company:

Registered address:

VAT Number:

having the legal capacity required to act on behalf of the company **[insert name of the entity]** hereby confirm that our company **authorises the [insert name of the tenderer] to rely on its financial and economic capacity in order to meet the minimum levels** required for the Call for tenders SANTE/2020/C3/087 - for the development, production, priority-purchasing options and supply of COVID-19 Vaccines for EU Member States.

Done at:

Name:

Position:

Signature:

Annex 6. Financial offer form

To submit an offer, this form must be filled-in electronically using the file "**Annex 6 Price schedule.xlsx**", printed and signed.

NB: If the contract will be awarded, information from this price schedule might be used in the APA.

Annex 7. Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, as approved by the Commission Decision C(2020) 4192 final of 18 June 2020

Annex 8. Draft ADVANCE PURCHASE AGREEMENT ("APA") for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States