



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Administration and Corporate Management Division

Guidebook for Tenderers

Submitting a tender in response to a procurement procedure organised by the European Medicines Agency (“the Agency”)

Disclaimer

This document is designed to help tenderers to submit their tenders in response to procurement procedures issued by the Agency for the supply of goods and services and also for works.

However, the information contained in this document is of a general nature only and is not intended to address the specific circumstances of any particular individual or entity. Therefore the Agency accepts no responsibility or liability whatsoever with regard to it.

Tenderers are requested to note that any information, questions or observations, of whatever kind, contained in this document can in no way be regarded as a commitment on the part of the Agency to enter into any contract. No binding commitment will be entered into until a procurement procedure is completed and the relevant contract signed. In the case of a framework contract, signature of the framework contract imposes no obligation on the Agency to purchase any goods or services. Only the implementation of a framework contract through either purchase orders and/or specific contracts is binding for the Agency.

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1. Legal framework

This section lists the main legal provisions applicable to procurement procedures organised by the Agency for the supply of goods, services and works.

1.1. Procurement procedure

1.1.1. Statutory provisions

The procurement procedure is governed by the following statutory provisions:

The European Union's **Public Procurement Directive 2014/24/EU of 26 February 2014** on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

Regulations **implementing** the above-mentioned Directive for the Agency, more particularly:

- The **Financial Regulation** applicable to the budget of the European Medicines Agency from 1 July 2019, as adopted by the Management Board on 13 June 2019¹;
- 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 Union² (hereinafter referred to as the "general Financial Regulation").

1.1.2. Other provisions

In addition to the above-mentioned primary and secondary legislation, it is worth noting that:

- principles arising from the **Court of Justice of the European Union's case law** in the field of procurement are binding on the Agency;
- prospective tenderers are legitimately entitled to expect the Agency to manage its procurement procedures in accordance with generally accepted principles arising from the **European Ombudsman's** decisions;
- By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996³ concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EC) No 883/2013 of the European Parliament and the Council of 11 September 2013 concerning investigations conducted by **the European Anti-Fraud Office (OLAF)**⁴, OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by European Union law for the protection of the financial interests of the Agency against fraud and other irregularities. Where appropriate, the findings may lead to recovery by the Agency.
- The Agency's staff is bound by a "**Code of Good Administrative Behaviour**" in their relations with the public. This includes the management of procurement procedures, subject to the restrictions laid down in the above-mentioned legal provisions.

¹ https://www.ema.europa.eu/en/documents/other/financial-regulation-applicable-budget-european-medicines-agency-1-july-2019_en.pdf

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31996R2185>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0883>

1.2. Resulting contract

Unless the procurement documents stipulate otherwise, contracts resulting from a procurement procedure issued by the Agency are governed by Union law (see 4.4. for further details on the contractual arrangements).

2. Basic information about the procurement procedures organised by the Agency

This document is primarily intended to give information on the procurement procedures for those procurements which have a value over the threshold of the Directive and which follow the open or restricted procedures. Tenders for goods and/or services with a value under €140,000 are normally concluded through consulting a number of candidates in a negotiated procedure and more information on this procedure can be found in Section 12. of this Guidebook.

2.1. Overview of procedure and e-tendering website

The procurement procedures described in this document follow either the open or restricted procedure laid down by the Directive and contracts are awarded on the most economically advantageous basis. This consists in one of three award methods: lowest price, lowest cost or best price-quality ratio. The Agency usually awards contract on the basis of a best price-quality ratio but the procurement documents will explicitly mention the procedure and the award method used for the procurement procedure concerned.

Any open or restricted procedure is subject to mandatory publication of a contract notice in the Official Journal of the European Union (OJEU) published by **Tenders Electronic Daily (TED)**: <https://ted.europa.eu/TED/main/HomePage.do>. The advertised contract notice will contain a link to the **e-tendering website at Tenders Electronic Daily** which will allow interested economic operators to view and download all the procurement documents relating to that particular procurement procedure on the **e-tendering website**.

Interested economic operators are advised to create an account by registering their details on the **e-tendering website** <https://etendering.ted.europa.eu/general/page.html?name=home>. Interested economic operators should **click 'login' on the left-hand menu, then click 'external' and then 'create an account'**.

Once logged in, economic operators are advised to subscribe to a particular procurement procedure on the **e-tendering website** to receive notifications for events such as the publication of new documents including Questions and Answers (Q&A) or updates of already published documents.

The Agency will also usually voluntarily announce launch of the procurement procedure for open and restricted procedures on its external webpage by indicating a link where the procurement documents are available on the **e-tendering website**:

<https://www.ema.europa.eu/en/about-us/procurement>

The Agency may also advertise its procurement procedure in other media however it is not obliged to do so and thus this, and the above website, should not be relied upon.

It is important to be aware of the differences between the various **stages** of a procurement procedure and the milestones associated with each stage:

1. The preliminary stage may start with the publication of a prior information notice in the OJEU, in which the Agency announces its intention to initiate a procurement procedure at a later date and

gives basic information about the subject matter of a possible future contract award. Tenderers should note that the publication of a prior information notice is not mandatory for the Agency. The aim is to give potential tenderers advance notice that a procurement procedure is going to be initiated and to allow them to prepare for it.

The **tendering stage** for open procedures starts with the publication of the procurement documents composed of a **contract notice** in the OJEU, the invitation letter, the tender specifications and their annexes and the draft contract. The OJEU contract notice contains detailed information about the procurement and triggers the application of a certain number of deadlines, which are binding on both the Agency and the tenderers. All the procurement documents can be downloaded from the **e-tendering website** at <https://etendering.ted.europa.eu/general/page.html?name=home>

This stage ends on the date indicated as the **deadline for the submission of tenders**.

2. The **evaluation stage** for open procedures starts with the **consideration of the tenders**. During this stage, the Agency assesses the tenders received against the notified exclusion, selection and award criteria as well as compliance with the minimum technical requirements stated in the procurement documents.
3. The **award stage** starts with the **signature of the award decision** by the Authorising Officer. This is followed by the **notification of the results** (see **11.1.**) to all the tenderers, both successful and unsuccessful simultaneously. Once the **contract** is signed with the successful tenderer, an **award notice** is published in the Official Journal of the European Union. This action closes the procurement procedure.
4. In the case of **restricted** procedures, the tendering stage starts in the same way with the publication of a **contract notice** in the OJEU. In a **restricted** procedure, candidates will be invited to express their wish to participate by providing documentation in relation to the first stage of the evaluation only, namely the pre-qualification stage or **evaluation of the exclusion and selection criteria** (see 9.1. and 9.2.). A pre-qualification questionnaire will be available on the **e-tendering website** to download and complete for this stage. The full tendering specifications will also be made available for information only. Once the first stage has been completed, a shortlist may be established of the most suitable candidates to be invited to submit a full tender. A minimum of five and a maximum of 20 candidates may be short listed but a range of 5-10 candidates will normally be invited to tender. It is to these short listed candidates only that an invitation to tender will be made through the **e-tendering website** via an email notification. Tenderers must follow the link in the email notification to download the invitation to tender letter and other procurement documents. Alternatively the Agency may decide to invite all candidates meeting the exclusion and selection criteria to tender. In such case all successful candidates would receive the email notification via the **e-tendering website**. Once the invitation to tender has been made through the email notification, the procedure continues in the same way as for the open tender, with tenders being submitted before a set deadline. The tenders are then considered and evaluated against the pre-established award criteria. The **award stage** is the same as for the open procedure.

3. Contacting the Agency about a procurement procedure

Please see section 2.1. on creating an account and registering details as well as subscribing to a particular procurement procedure on the **e-tendering website**.

The Agency will not accept any questions submitted by e-mail and that registration to the **e-tendering website** and subscription to this call for tender for any future notifications is the tenderer's

responsibility. Tenderers will not receive individual notifications of the publication of document updates and/or Q&A directly from the Agency via our email address.

Contacts between the Agency and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

Before the final date for submission of tender:

All documents related to a call for tender are downloadable on the **e-tendering website** and visible following the e-tendering link published in the Official Journal contract notice and link on the Agency's webpage, but in order to use some options on the **e-tendering website**, users will need to log in. Once logged in, users will have the option to 'subscribe' to a call for tender which will mean they receive notifications for events such as publication of new documents. Moreover, this will allow users to ask questions related to the call for tender.

At the request of the tenderer, the Agency may provide additional information solely for the purpose of clarifying the procurement documents. Any such request for information will be published on the **e-tendering website**. Requests for additional information received less than six working days before the closing date for submission of tenders will not be processed for practical reasons.

The Agency may, on its own initiative, inform the interested parties of any error, inaccuracy, omission or any clerical error in the invitation to tender or its annexes. Any such additional information will be published on the **e-tendering website**. It is the tenderer's responsibility to check for updates and modifications.

After the opening of tenders:

If obvious clerical errors in the tender need to be corrected or confirmation of a specific or technical element is necessary, the Agency will contact the tenderer provided this does not lead to substantial changes to the terms of the submitted tender.

4. Considering whether or not to submit a tender

This section contains important information which will help tenderers take an informed decision on whether or not to commit resources to the submission of a tender in response to a procurement procedure.

4.1. How to understand the exact scope of the contract

The subject matter of the contract is mentioned in the prior information notice (if applicable) and the contract notice published in the OJEU, and described more fully in the procurement documents. In order to understand the exact scope of the contract, the aspects mentioned below should also be considered by the tenderer.

4.1.1. Volume of the contract

To guide the tenderer in preparing a tender, the procurement documents contain certain indications on the foreseeable volume of goods and/or services required under the contract and will normally indicate an estimated contract value.

However, although the Agency always tries to give its best estimate in good faith, tenderers should be aware that any information on volume or estimated value is purely indicative and shall not be binding on the Agency and should not be considered as a warranty as to the probable value of the contract.

In the case of framework contracts, the total value of the contract will ultimately depend on the orders which the Agency may place through either purchase orders or specific contracts (see 4.4.).

4.1.2. Lots

When a procurement procedure is divided into lots, this is explicitly mentioned in the procurement documents. In this case, unless stated otherwise in the procurement documents, tenderers **may submit tenders for one lot only, or any combination of lots, or for all the lots.**

Each individual lot is assessed independently of any other lot and considered only in its entirety. Tenderers may therefore not submit a tender:

- that covers only part of a lot,
- that is declared as dependent, or being conditional, on the award of any other lots included within the particular procurement procedure.

The Agency will disregard any statement to this effect contained in a tender, and further reserves the right to reject such tenders without further evaluation on the grounds that they do not comply with the procedure.

4.1.3. Variants

Variants are departures from any technical or financial requirements of the tender, or from any contractual conditions, described in a procurement procedure.

Unless stated otherwise in the procurement documents, **variants are not permitted.**

The Agency will disregard any variants described in a tender, and further reserves the right to reject such tenders without further evaluation on the grounds that they do not comply with the procurement documents.

4.1.4. Product names and trademarks

Unless stated to the contrary, whenever the procurement documents mention a specific product name or trademark and a sufficiently detailed and intelligible description of the subject matter of the contract is not possible, such mention should be understood as referring to the product belonging to the trademark owner in question **or its equivalent.**

4.2. Implications of submitting a tender

4.2.1. Acceptance of Agency contractual terms and waiver of own business terms

The action of submitting a tender in response to a procurement procedure issued by the Agency shall be deemed to imply that tenderers:

- **accept** all the terms and conditions as stipulated in the tendering specifications and all other documents related to the procurement including the draft contract; and
- **waive** their own terms of business such that any resultant contractual relationship shall be governed exclusively by the terms of the tender.

The Agency will disregard any qualification, disclaimer or intention to the contrary contained in a tender, and further reserves the right to reject such tenders without further evaluation on the grounds that they do not comply with the procurement documents.

Unless the procurement documents stipulate a different time period, tenderers will be bound by their tender for **six months** from the deadline for submission of tenders.

4.3. No obligation to award

When awarding a contract, the Agency undertakes to compare the tenders in the light of the criteria laid down in the procurement documents.

However, the fact of publishing a procurement procedure **does not oblige the Agency to award** the contract to a tenderer simply because its tender fulfils those criteria. It also reserves the right to decide not to award the contract to any tenderer and to cancel the procedure at any time before award.

The Agency is not liable for any compensation in such circumstances.

4.4. Nature of the contractual relationship resulting from the award of the contract

The procurement documents will clearly indicate the type of contract that the Agency is seeking to enter into and its duration.

Sometimes the Agency will state that the contractual relationship between the Agency and the successful tenderer will be governed by a special type of contract known as a "**framework contract**".

It should be stressed that framework contracts involve **no direct commitment** and, in particular, do not constitute orders *per se*. Instead, they only lay down the legal, financial, technical and administrative provisions governing the relationship between the Agency and the contractor during their period of validity and should orders be placed thereunder.

Actual orders will be placed only after the framework contract is signed, in the form of "**specific contracts**" or "**purchase orders**" concluded in pursuance to the framework contract.

Unless specified otherwise in the procurement documents, only one framework contract will be signed for a given lot.

The tendering specifications will include:

- a draft version of the framework contract. On completion of the tendering procedure, this draft will be finalised as necessary in line with the successful tender (e.g. prices (etc.));
- in some cases, additional documents will be annexed to the framework contract (e.g. service level agreements, master licences (etc.)).

Sometimes, the Agency may indicate that it wishes to conclude a multiple cascading framework contract with a number of contractors. In such a case a system of priority would be established whereby specific contracts or purchase orders would be placed with the first priority contractor. If the goods and/or services are unavailable from the first priority supplier, the specific contract or purchase order would then be placed with the second priority contractor and so on. A minimum of two framework contracts in priority order will constitute a cascade.

The Agency may also conclude multiple framework contracts with a number of contractors where not all the terms are laid down in the framework contract and without a system of priority being

established. In such cases the Agency may reopen competition and ask the parties to compete on the basis of more precisely formulated terms. The Agency will consult the contractors in writing, fixing a time limit which is sufficiently long to allow tenders to be submitted in writing. The Agency would then award each specific contract to the contractor which has submitted the best tender on the basis of the award criteria set out in the procurement documents.

When preparing a tender, tenderers should take full account of the contract details, the draft contract and any other documents included in the procurement documents, as they will define and govern the contractual relationship to be established between the Agency and the successful tenderer.

4.5. Participation of other EU institutions, agencies and bodies

The Agency may issue **inter-institutional or inter-agency calls for tenders**. If this should be the case, the procurement documents will explicitly state this fact and specify exactly which awarding authorities the resulting contract(s) will apply to.

The participation of other EU institutions, agencies and bodies may have important consequences for the future contractor, in particular as regards the volume of the contract and the places of delivery.

In summary, inter-institutional procedures are handled as follows:

- The Agency publishes the procurement procedure on behalf of all the participating institutions, agencies and bodies and arranges for evaluation of the tenders. The Agency signs and manages the resulting contract (including any amendments thereto) or framework contract on behalf of all the participating institutions, agencies and bodies but each contracting authority shall issue its own specific contracts and/or purchase orders to implement the framework contract (where applicable).

At the time of writing, the EU Institutions, Agencies and other bodies are those listed on the website mentioned in the annex "References".

If a procurement procedure is not inter-institutional or inter-agency, only the Agency is entitled to use the resulting contract or framework contract.

4.6. Tax exemption

The Agency is exempt from all duties and taxes, 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 annexed to the Treaty establishing a single Council and a single Commission of the European Communities. The Governments of Member States of the European Union grant this exemption either through refunds upon presentation of documentary evidence, or by immediate exemption. The Agency will give the successful tenderer instructions regarding this point and whether VAT may be charged and reclaimed or must be omitted from invoices.

4.7. Further information on the activities of the Agency

Tenderers will find a number of documents which may be of interest to them on the Agency's external website. The website address is: <https://www.ema.europa.eu>.

4.8. Participation in the Agency's tenders

Participation in the Agency's tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country

which has a special agreement with Union in the field of public procurement under the conditions laid down in that agreement.

Participation in procurement procedures is also open to international organisations as defined in article 156(1) of the general Financial Regulation.

The Agency can therefore accept offers from and sign contracts with tenderers from the EU Member States, EEA countries and any other country which has an international agreement with the Union in the field of public procurement. The tender procedures of the Agency are not, however, open to tenderers from countries which have ratified the Multilateral Agreement on Government Procurement ("GPA").

5. Collaborating with other economic operators

An economic operator may, where appropriate and for a particular contract, rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Agency that it will have at its disposal the resources necessary for the performance of the contract by producing a commitment by those entities to that effect.

Economic operators can consider two ways of collaborating in a tender: either as joint partners in the tender or through subcontracting. Unless stated otherwise in the procurement documents, both **joint tenders** and **subcontracting** are allowed in response to a procurement procedure issued by the Agency. Tenders may even combine both approaches.

In any case, the tender must specify very clearly whether each economic operator involved in the tender is acting as a partner in a joint tender or as a subcontractor (this also applies where the various economic operator involved belong to the same group, or even where one is the parent company of the others). The tendering specifications may contain questionnaires to be completed for this purpose. Selection criteria may apply per tenderer, per economic operator (member of the group in a joint tender or subcontractor) or to at least one economic operator, as stated in the procurement documents.

The implications of these two modes of collaboration are very different. So that tenderers can understand them both fully, they are outlined below.

5.1. Joint tenders

5.1.1. Liability for performance of the contract

Partners in a joint tender shall be required to assume joint and several liability towards the Agency for the performance of the contract as a whole.

Statements saying, for instance:

- that one of the partners of the joint tender will be responsible for part of the contract and another one for the rest without recourse to the other for performance, and/or
- that more than one contract should be signed if the joint tender is successful,

are thus incompatible with the principle of joint and several liability. The Agency will disregard any such statement contained in a joint tender, and further reserves the right to reject such tenders without further evaluation on the grounds that they do not comply with the procurement documents.

5.1.2. Assessment of joint tenders

Joint tenders will be assessed as follows, unless indicated otherwise in the procurement documents:

- The exclusion criteria (see 9.1.) will be considered in relation to the tenderer and each proposed member individually.
- For the evaluation of the selection criteria (see 9.2.), an assessment shall normally be made in relation to the combined capacities of all the members of the grouping as a whole. Such criteria may apply individually only where it is relevant in view of their nature.
- The award criteria (see 9.3.) will be considered in relation to the tender as a whole.
- The proposed partners in a joint tender may not be changed, revised or replaced during the course of any procurement procedure following submission of that tender without our permission or at all after selection, since evaluation will have taken into account their individual legal identity (corporate entity or otherwise) and capacity as well as their combined capacities. For the avoidance of doubt, this will also apply to joint tenders selected for all procedures which then may become negotiated procedures by operation of the appropriate procurement rules.

5.1.3. Confirmation of status

If tenderers intend to tender with a partner and have already set up a consortium or similar entity to that end, this fact should be mentioned in the tender, together with any other relevant information in this regard.

If tenderers intend to submit a joint tender but have not yet taken this step, they should be aware that, if they are awarded the contract, the Agency will require them to give a formal comfort as to their status in connection with their collaboration before the contract is signed. This can take the form of:

- The joint tenderers forming an independent entity with legal personality recognised by a Member State [and guaranteed by both parties]; or
- An entity without legal personality but tendering sufficient joint and several protection of the Agency's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association); or
- The signature by all the partners of a "power of attorney" authorising each partner to bind each other to perform the contract, which provides for a less onerous form of cooperation whilst still safeguarding the Agency's contractual interests.

5.2. Subcontracting

5.2.1. Liability for performance of the contract

Certain operational tasks provided for in the contract may be entrusted to subcontractors, but the main contractor retains full liability towards the Agency for performance of the contract as a whole.

Accordingly:

- The Agency will treat all contractual matters (e.g. payment) as being exclusively with the main contractor, whether or not the tasks are performed by a subcontractor; however if a subcontractor provides the whole or a large part of the financial capacity, the Agency may demand that the subcontractor also signs the contract, or alternatively, the subcontractor may commit itself to execute the contract jointly and severally with the contractor by providing a letter or intent to that effect.

- Under no circumstances can the main contractor avoid liability towards the Agency on the grounds that the subcontractor is at fault.

5.2.2. Documents to be provided

If a tenderer's tender envisages subcontracting, the tender must include a document clearly stating the name(s), address(es) and registration numbers of the proposed subcontractors in addition to the roles, activities and responsibilities of subcontractor(s), and specifying the volume / proportion of the tender being subcontracted for each subcontractor. In case of *intra muros* services (performed at the Agency's premises) the name, contact and authorised representatives of subcontractors must also be provided.

A signed letter of intent by each subcontractor must also be provided stating its unambiguous undertaking to collaborate if the tenderer wins the contract and the extent of the resources that it will put at the tenderer's disposal for the performance of the contract, unless, in the case of works contracts, the identity of the subcontractor is unknown at the time of tendering.

If so requested, documents regarding the exclusion and/or selection criteria for the proposed subcontractor(s).

5.2.3. Assessment of subcontractors

Tenders involving subcontracting will be assessed as follows unless indicated otherwise in the contract notice and/or tendering specifications:

- The exclusion criteria (see 9.1.) will be considered in relation to the tenderer and each proposed subcontractor individually.
- For the evaluation of the selection criteria (see 9.2.) for economic and financial capacity a consolidated evaluation will take place where a certain overall turnover is stipulated.
- For the evaluation of the selection criteria (see 9.2.) for technical and professional capacity, an assessment shall be made in relation to the combined capacities of the tenderer and the proposed subcontractor(s). Such criteria may apply individually only where it is relevant in view of their nature.
- The award criteria (see 9.3.) will be considered in relation to the tender as a whole.

Where subcontracting is proposed, tenderers should ensure that they maintain the same subcontractors throughout a procurement procedure as the evaluation will be made in relation to the individual legal identity (corporate entity or otherwise) and capacity as well as the combined capacities of both the tenderer and the subcontractor(s). The Agency shall require a tenderer or contractor to replace a subcontractor where it does not fulfil the exclusion criteria or a relevant selection criterion.

5.2.4. Replacement of subcontractors

Following execution of the contract, the contractor will need the Agency's express written authorisation to replace a subcontractor with another and/or to subcontract tasks for which subcontracting was not envisaged in the original tender.

6. Preparing a tender

This section describes how a tenderer should go about preparing a tender.

6.1. Downloading the procurement documents

In the case of an **open** procurement procedure, at the same time that the contract notice is published in the Official Journal of the European Union, the procurement documents will be made available for electronic download on the **e-tendering website** at Tenders Electronic Daily (see 2.1. & 3.). Answers to questions of general interest and any other important information about the procurement procedure arising during the tendering period will also be published through the **e-tendering website**.

In the case of a **restricted** tender procedure, if a candidate is invited to submit a tender, an email notification will be sent through the **e-tendering website**. The link contained in this email should be followed in order for the candidate to download the invitation to tender letter containing important information about submission of the tender and the deadlines and to view the other procurement documents.

6.2. Clarifying the tendering specifications

During the tendering stage, tenderers may ask questions (including requests for further information) about specific issues arising from the procurement documents.

To this effect tenderers for restricted or open procedures should formulate their questions **through the e-tendering website, within the applicable deadline** stipulated. The Agency is not obliged to reply to any questions arriving after the applicable deadline.

The Agency will review all questions received with the utmost attention before taking one of the following courses of action:

- If it decides that a question is of general interest to potential tenderers, it will publish its reply to all tenderers through the question and answer facility in the **e-tendering website**. All such questions will first be rendered anonymous, and the Agency's reply should thereafter be regarded as an integral part of the procurement documents.
- In all other cases, the prospective tenderer who raised the question will receive an individual answer.

6.3. Drawing up a tender

6.3.1. Language

A tender may be drawn up in **any of the official languages** of the European Union (at the time of writing, these are listed on the website mentioned in the annex "References"). The Agency prefers, however, to receive documentation in English. Nonetheless, the choice of language will be ignored for the purposes of considering the tender.

6.3.2. Replying to mandatory questions

Tenderers should pay particular attention to any questions which may be labelled "Mandatory", in particular the **minimum technical requirements** which the Agency shall make known to the tenderers in the procurement documents and for which tenderers must sign a declaration of

compliance. **These questions require an unconditional answer.** If no answer is given or if an answer is qualified in any way (e.g. a “yes, but ...” answer), the tender will be disqualified.

If a tenderer is not in a position to provide an unqualified answer to all the mandatory questions, a tender should not be submitted.

6.3.3. Confidential information

The Agency undertakes to protect tenderers’ commercial interests by treating all the information contained in a tender as confidential as amongst the tenderers and the public in general.

In particular, it will not disclose any information where such disclosure would hinder application of the law, be contrary to public interest, harm tenderers’ legitimate business interests or distort fair competition.

6.3.4. Protection of personal data

In certain cases, the follow-up of tenderers’ responses to the procurement procedure will require the recording and further processing of personal data (for example, name, contact details, address or CV of natural persons). Such data will be processed by the Agency in accordance with Regulation (EU) No EU 2018/1725 of the European Parliament and of the Council of 23 October 2018 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 and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC⁵.

Except if mentioned otherwise, replies to questions and personal data requested are necessary for the purpose of assessing a tender according to the tendering specifications and will only be processed by the Evaluation Committee (see 9.) for that purpose on a need-to-know basis.

Details concerning the processing of tenderers’ personal data in the context of public procurement procedures are available on the Agency’s website at:

https://www.ema.europa.eu/en/documents/other/privacy-statement-processing-personal-data-context-public-procurement-procedures_en.pdf

So that the Agency can take appropriate steps to this effect while assessing the tenders, any CVs (or similar documents) tenderers are asked to submit relating to their staff should not indicate any names. Instead, each CV should bear a number only, and the tender should include a list showing the association between these numbers and actual names. This list of names is not used for the purposes of evaluation of a tender.

Tenderers are also informed that for the purposes of safeguarding the financial interest of the European Union, personal data may be transferred to internal audit services, to the European Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office (OLAF).

Tenderers’ personal data may be registered in the Early Detection and Exclusion System (EDES) if in one of the situations mentioned in Article 136 of the general Financial Regulation⁶. For more information, see the Privacy Statement at:

http://ec.europa.eu/budget/library/explained/management/protecting/privacy_statement_edes_en.pdf

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

⁶ 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 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

Please note that processing of personal data by tenderers (candidates, selected contractors, subcontractors or other parties) in connection with a procurement contract must comply with EU data protection and in particular, Regulation (EU) 679/2016⁷, the General Data Protection Regulation.

The selected contractors may act as an individual data controller, a joint controller together with EMA or as a data processor of EMA. In each case the contractor shall process data in compliance with the respective data protection provisions of the contract.

In case the selected contractor acts as a processor of EMA with regard to personal data handled under the contract in the sense of Article 29 of Regulation (EU) 2018/1725, the contractor shall:

- only process personal data on documented instructions of EMA as the data controller,
- ensure that persons processing personal data have committed themselves to confidentiality,
- undertake appropriate technical and organisational measures to ensure the confidential and secure processing of personal data needed for the implementation of the contract,
- delete or return to EMA all personal data after the end of the provision of services,
- make available to EMA all information necessary to demonstrate compliance with the obligations pursuant to Regulation (EU) 2018/1725 and allow for or contribute to audits and inspections by or on behalf of EMA,
- notify personal data breaches to EMA,
- when engaging a subcontractor, shall impose the same obligations with regard to personal data protection.

6.3.5. Formal aspects

Great importance should be attached to how the tender is presented to the Agency. The following guidelines lay down **a minimum standard** which must be met in all cases.

6.3.5.1. Questionnaires

The tender should be drawn up by filling in any of the ad hoc questionnaires or forms which may be included in the procurement documents, which will be made available electronically on the **e-tendering website** as described in 6.1. . The numbering of the questionnaires should not be altered.

6.3.5.2. Format of tender submission

As far as possible, the tender response should be drawn up and submitted using word-processing or desktop publishing software, in a font size giving a legible result on paper. All documents should be in either Adobe Portable Document Format (.pdf) or in standard MS Office format (i.e. .doc and .xls).

If the tender, or any part of it, is hand-written, it should be **legible**, so as to rule out any doubt whatsoever as to the words or figures used.

6.3.5.3. All answers must be concise and clearly drafted.

Where possible, tenderers should answer in the space provided on the questionnaire or form. However, if tenderers need additional space, the reply should be made on a separate sheet and annexed to the questionnaire or form, unless a maximum length of reply is stipulated in the

⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

procurement documents. Such annexed replies (which should not exceed two pages of A4 paper per question) must be **clearly referenced**, and the reference noted on the questionnaire in the space provided for the reply.

6.3.5.4. Complete answers

Answers must be complete. Where a question has not been answered, the Agency will make no assumption to the benefit of the tenderer as to what the answer might have been and will award no points for it.

Similarly, where only a partial answer is given, the Agency will award points only for the part of the question answered.

6.3.6. Specific requirements for the financial offer

6.3.6.1. Financial offers

Financial offers must be drawn up on any ad-hoc form, usually referred to as the “costing sheet”, which may be included in the questionnaires or forms annexed to the tendering specifications. Tenderers must complete such forms in full without modification. If tenderers change this form in any way, the tender will be disqualified.

6.3.6.2. Prices must be quoted:

- in Euros;
- free of all duties and taxes (in particular VAT which may be added in later), for the reasons stated in 4.6. ;
- inclusive of all costs and expenses directly and indirectly connected with the goods and/or services to be supplied (unless indicated otherwise in the procurement documents).

6.3.6.3. Unambiguous financial offers

The financial offer should be completely unambiguous. A tender will be disqualified if it contains any statements preventing an accurate and complete comparison of the tenders (such as “To be discussed”, “Depending on x”, etc.) or referring to external circumstances or extraneous documentation (such as an already existing but separate contract). In the case of some works contracts, external circumstances may require only a provisional financial offer. If this is so, it will be indicated in the procurement documents.

6.4. Preparing a tender for submission

Tenders for open or restricted procurement procedures must be submitted exclusively via the electronic submission system (e-Submission) available from the TED eTendering website⁸ and accessible on the Funding and Tenders Opportunities portal (F&T portal)⁹.

For detailed instructions tenderers may also consult the e-Submission Quick Guide available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/esubmission/quickguidepp_en.pdf.

The supported browsers, file types, size of attachments and other system requirements can be consulted at: <https://webgate.ec.europa.eu/fpfis/wikis/x/Oo5kI>. In case of technical problems,

⁸ <https://etendering.ted.europa.eu/general/page.html?name=home>

⁹ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

tenderers should contact the e-Submission Helpdesk (see contact details in the e-Submission Quick Guide) as soon as possible.

In order to submit a tender using e-Submission, tenderers (each member of the group in the case of a joint tender) will need to register in the European Commission's [Participant Register](#)¹⁰ - an online register of organisations participating in EU calls for tenders or proposals. On registering each organisation obtains a Participant Identification Code (PIC, 9-digit number) which acts as its unique identifier in the above register. Instructions on how to create a PIC can be found on this [page](#)¹¹. Tenderers already registered in the Participant Register shall reuse their existing PICs when preparing tenders in e-Submission.

7. Submitting a tender

The precise modalities about how to submit an offer to EMA and the documents and information which should be included with the offer shall be clearly explained in the invitation to tender letter which forms part of the procurement documents.

In general, tenders in response to an open call are submitted using the e-Submission application¹².

Tenders in response to a negotiated procedure under EUR 140,000 in value, reopening of competition and restricted procedures from calls for expression of interest are submitted by electronic mail to a secure e-mail box. In such cases tenders submitted to other e-mail addresses, apart from those stipulated in the invitation to tender, shall be immediately rejected for failing to comply with the tender instructions.

The **deadline for submitting tenders** will be indicated in the procurement documents. A tender received after the time-limit for receipt of tenders will be rejected. The submission receipt provided by e-Submission with the official date and time of receipt of the submission (timestamp) constitutes proof of compliance with the time-limit for receipt of tenders. In cases where tenders are submitted to an e-mail box, the date and time of the auto reply e-mail from the Agency serves as proof of receipt and proof of date and time.

Tenderers must ensure that their submitted tenders contain all the information and documents required by the Agency at the time of submission as set out in the procurement documents.

8. Opening of the tenders

The Agency is required to appoint an Opening Committee for all tenders exceeding €140,000 in value. In the case of an **open** procedure, an Opening Committee will open all the tenders on the date, and at the time and place indicated in the procurement documents. Each tenderer may send one representative to the opening session in the case of **open** procedures. If tenderers choose to do so, they should notify the name of that person by email to the Agency, no later than two working days, or any other period indicated in the procurement documents, before the opening session, failing which the Agency reserves the right to refuse to admit any representative to the opening session. The Agency shall require any representative to provide proof of identity.

The public part of the opening session will be strictly limited to the following aspects:

- Verification that each tender has been submitted correctly (in particular, that the deadline for submission has been complied with);

¹⁰ <http://ec.europa.eu/research/participants/portal/desktop/en/home.html>

¹¹ <https://webgate.ec.europa.eu/fpfis/wikis/x/sYXvIg>

¹² <https://etendering.ted.europa.eu/general/page.html?name=home>

- Announcement of the tenders received for each lot. The names announced will be those of the economic operators having sent or deposited tenders, as they appear on the covering letters, envelopes, receipts and/or routing slips. Please note that these names may or may not correspond to the precise legal identity of the actual tenderers and may or may not include other economic operators involved in the tenders (e.g. as partners in joint tenders).

The tenderers' representatives will be required to sign an attendance sheet but will not receive any minutes of the session at the public opening.

The Opening Committee will play no further role in the procedure.

If a tender is found to be non admissible to the procedure as it has not complied with the instructions for submission, the Agency shall inform that tenderer without delay.

9. Assessment of tenderers and tenders

During the assessment stage, tenderers may not contact the Agency on their own initiative (see also 10.).

The Agency is required to appoint an Evaluation Committee for all tenders exceeding €140,000 in value. The tenders will be assessed by an Evaluation Committee working under conditions of confidentiality and absence of conflict of interest. Once the assessment is completed, the Evaluation Committee will draw up a report for the competent authorising officer, who will take the final decision on the award of the contract.

Tenders will be assessed in the light of the criteria explicitly announced beforehand in the procurement documents¹³.

In addition to the information contained in the tenders, the Agency reserves the right to use any other information from public or specialist sources, provided that this use complies with the general principles of transparency, proportionality, equal treatment and non-discrimination.

9.1. Exclusion

The sole purpose of the exclusion criteria is to determine whether a tenderer is qualified to participate in the tender procedure.

The exclusion criteria which shall apply are set out in Articles 136 and 137 of the general Financial Regulation¹⁴.

All tenderers (and candidates in a restricted procedure) must provide a declaration upon honour, an example of which is given in Annex II of this Guidebook, duly signed and dated, stating that they are not in one of the exclusion situations. This same declaration may also be requested from subcontractors.

In the case of an open procedure, only the successful tenderer to whom a contract is to be awarded will be required to show that it is not in one or more of the situations listed above by providing the required **evidence** in relation the exclusion criteria within a time limit defined by the Agency and prior

¹³ If the restricted procedure is used the process is split into :

Pre-selection stage: candidates submit applications containing only the documentation required for Phase 1 (Exclusion) and Phase 2 (Selection). These applications are then evaluated to select the candidates who will be entitled to submit a tender, hence becoming tenderers. Invitation to tender stage: pre-selected candidates submit tenders containing the documentation required for Phase 3 (Evaluation according to award criteria). The contract is awarded (Phase 4) once these tenders have been assessed.

¹⁴ 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

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

to the signature of any contract. The evidence required is indicated at the end of the sample declaration upon honour in Annex II of this Guidebook.

IMPORTANT NOTICE: As the time limit for submitting documentation for documentary evidence for exclusion criteria in the case of an open procedure is in general 10 calendar days from the notification of the contract award, the Agency strongly recommends that the tenderer starts gathering the requested documents (especially in case of joint tender/subcontracting, including the relevant documents for consortium partners/subcontractors) as soon as possible in order to have the documents ready to be sent to the Agency in case it is awarded the contract. This will reduce the time line to sign the awarded contract with the Agency. However, the Agency shall not sign the contract with the successful tenderer until a standstill period of 10 calendar days has elapsed, running from the day after the simultaneous dispatch by email of the notification to tenderers (those rejected and the successful tenderer(s)).

In a restricted procedure, where a maximum number of candidates to be invited to tender has been specified, all candidates will be required to provide both the declaration upon honour as well as the evidence.

Depending on its analysis of risks, the Agency may decide not to require the above-mentioned declaration upon honour for contracts with a value up to 14,999 Euros.

For other tenders with a value up to the threshold of the Public Procurement Directive only a signed and dated declaration upon honour is required without supporting evidence, unless the Agency has doubts as to whether the tenderer to whom the contract is to be awarded is in one of the situations of exclusion. In such a case the Agency may require the tenderer to provide the evidence indicated at the end of the sample declaration upon honour in Annex II of this Guidebook.

If a sworn statement is provided for the evidence, this should be signed by the person(s) empowered to represent the tenderer and sign the contract if the tender is successful and dated less than four months before the final date for submission of tenders.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the 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.

The competent authorising officer at the Agency may decide that exclusion criteria can be evaluated by the Agency staff member(s) outside the evaluation committee, provided that no conflict of interest exists.

9.2. Selection

Tenderers will be selected if they can prove that they have sufficient economic and financial capacity, on the one hand, and sufficient technical and professional capacity, on the other hand.

In the selection phase, assessment focuses on the quality of the track record and not on the quality of the tender. Accordingly, information relating to the qualitative proposal or the financial offer should not be introduced in this part of the tender.

Unless indicated otherwise in the procurement documents, tenderers for open procedures will normally be required at the time to provide a declaration upon honour of compliance with selection criteria. An example of this declaration upon honour is given in Annex II of this Guidebook. In such case,

evidence of fulfilment of the selection criteria will be requested later within a time limit defined by the Agency.

For tenders with a value less than €140,000 the Agency may dispense with the requirement for evidence in relation to selection criteria, according to its assessment of the risks involved. In such a case no pre-financing shall be made by the Agency.

The competent authorising officer at the Agency may also decide that selection criteria can be evaluated by the Agency staff member(s) outside the evaluation committee, provided that no conflict of interest exists.

9.2.1. Economic and financial capacity

In order to prove that tenderers have sufficient economic and financial capacity to perform the contract, the Agency may require in particular that:

- Economic operators have a certain minimum yearly turnover, including a certain minimum turnover in the area covered by the contract;
- Economic operators provide information on their annual accounts showing ratios between assets and liability;
- Economic operators provide an appropriate level of professional risk indemnity insurance.

For the purposes of turnover, the minimum yearly turnover shall not exceed two times the estimated annual contract value, except in duly justified cases linked to the nature of the purchase, which the Agency shall explain in the procurement documents.

For the purposes of annual accounts showing ratios between assets and liability the Agency shall explain the methods and criteria for such ratios in the procurement documents.

The Agency shall define in the procurement documents the evidence to be provided by an economic operator to demonstrate its economic and financial capacity. It may request in particular one or more of the following documents:

- Appropriate statements from banks or, where appropriate, evidence of relevant professional indemnity insurance;
- Financial statements or their extracts for a period equal to or less than the last three years for which accounts have been closed;
- A statement of the economic operator's overall turnover and, where appropriate, turnover in the area covered by the contract for a maximum of the last three financial years available.

If for any valid reason, the economic operator is unable to provide the references requested by the contracting authority, it may prove its economic and financial capacity by any other document which the Agency considers appropriate.

If an economic operator 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.

9.2.2. Technical and professional capacity

The criteria used to check whether a tenderer has sufficient technical and professional capacity to perform the contract, as well as the minimum levels or requirements and evidence required to that effect, will be listed **in the procurement documents**. These criteria and levels/requirements will relate to the tenderer's capacity to implement the contract.

9.3. Evaluation and award criteria

In this phase, tenders are compared with each other by evaluating them both from a technical¹⁵ and a financial point of view.

9.3.1. Qualitative evaluation (award criteria)

The qualitative evaluation of the tenders will be based on the criteria listed **in the procurement documents**.

Within the list of qualitative award criteria, the Agency may also adopt and notify of additional provisions such as those listed below, to ensure that the qualitative assessment takes full account of its needs. This will entail:

- The assignment of a **weighting factor** to each criterion;
- The possible stipulation of a **minimum threshold** for each criterion and/or for the qualitative award criteria as a whole (tenders not reaching such thresholds would be automatically disqualified).

Unless stated otherwise in the procurement documents, no minimum thresholds will be applied.

At the end of the qualitative evaluation, each tender will be assigned **a score for quality**.

9.3.2. Financial evaluation (award criteria)

The financial evaluation of the tenders will be based on the prices tendered and in accordance with the methodology set out in the tendering specifications. Tenderers should not give ranges of prices, unless it is specifically mentioned that this is acceptable.

The result of the financial evaluation will be **a price** representing:

- Either the global cost of the tender over the whole duration of the contract, unless indicated otherwise in the procurement documents;
- Or, in the case of a framework contract, the cost of a pre-defined scenario which —although it may represent only part of the total cost— is sufficiently significant for the purposes of comparing the tenders with each other, unless indicated otherwise in the procurement documents.

9.4. Award of the contract

Unless stated otherwise in the procurement documents, the Evaluation Committee will rank all the tenders received according to the pre-defined and published qualitative and financial award criteria. This will lead to the identification of which tender presents the most economically advantageous offer.

¹⁵ If the lowest price procedure is used (see §2.1), there are no qualitative award criteria. The contract will be awarded to the tender which, while being admissible and satisfying the terms of the procurement documents, tenders the lowest price.

In order to do so, the Evaluation Committee will use the weightings and any methodology specified in the procurement documents.

10. Clarifying the tenders

Once the tenders have been opened, the Agency may contact tenderers in writing to obtain further clarification on specific points of a tender or to correct obvious clerical errors. Tenderers should be prepared to reply to such requests for clarification within a very short deadline as stated in the request for clarification.

Such contacts must not lead to any alteration of the terms of the tender. More particularly:

- Tenderers must not modify a tender or add any new elements to it (other than purely administrative documentation). The reply must therefore make clear reference to the relevant information already present in the file.
- Where the financial offer is concerned, tenderers must not add any new prices, but only explain the offer on the basis of elements already present in the file, which should be explicitly mentioned.

If tenderers fail to observe these restrictions, their reply may be disregarded. If the reply plainly contradicts the original tender, the Agency reserves the right to disqualify the tender.

11. Outcome of the procurement procedure

During the evaluation period, the Agency will not provide any information on an ongoing procurement procedure. The only contacts allowed with tenderers are those mentioned in 10. . If a tenderer is not contacted, this should not be regarded as either a positive or a negative sign.

Tenderers will be informed of the outcome of the procurement procedure in the three ways outlined below.

11.1. Notification of results

As soon as the competent awarding officer has signed the award decision, a **notification letter** will be sent simultaneously to all tenderers; letters to unsuccessful tenderers will state the grounds on which the decision was taken. This will normally be sent by e-mail; it is the responsibility of the tenderer to provide in its tender submission a contact email address which is monitored regularly and to inform the Agency promptly of any change.

Please note, however, that the dispatch of these letters does not constitute the award of the contract. This will not be completed until the contract has been signed by the successful tenderer and the Agency.

In the case of a contract value exceeding the relevant thresholds of the Public Procurement Directive, **the Agency undertakes not to sign the contract until a period of at least fifteen calendar days has elapsed following the dispatch of the notification letters (unless the letters have been dispatched by electronic means whereby the period shall be reduced to 10 calendar days)**, so that unsuccessful tenderers can take the steps described in 11.2. below if thought appropriate. The normal method of dispatch by the Agency is e-mail. Any contract signed before this period shall be null and void.

In cases where the Agency wishes to sign a contract by negotiated procedure for works, supplies or services provided only by a particular economic operator, without prior publication of a contract notice in the Official Journal, the contract may not be signed until ten calendar days have expired following

the date of publication of a pre-award notice in the Official Journal. The competent authorising officer may suspend the signing of the contract for additional examination if this is justified by the requests or comments received. Any contract signed before expiry of this period shall be null and void.

11.2. Additional information

If tenderers are notified that a tender has not been successful, tenderers which are not in a situation of exclusion and whose tenders are compliant with the procurement documents may request additional information in writing to the Agency. This information shall be given in a **follow-up letter** providing further details in writing, such as the name of the tenderer(s) to whom the contract is awarded and the characteristics and relative advantages of the successful tender, the price paid or contract value, whichever is appropriate. However, the Agency may not disclose any information affecting the commercial interests of other tenderers (see 6.3.3.).

11.3. Award notice

Once the contract is signed, the Agency will publish an award notice in the Official Journal of the European Union summarising the results of the procurement procedure, where the contract value exceeds the relevant threshold of the Public Procurement Directive.

For contracts with a value below the threshold of the Directive, the Agency is obliged to publish before 30 June of each year a list of procurement contracts concluded during the previous year with values of between €15,000 and €138,999 on the Agency's external webpage:

<https://www.ema.europa.eu/en/about-us/procurement#calls-for-tender-worth-€15,000---€140,000-section>

The Agency shall also publish an annual list of contracts on its external webpage for modification of contracts below the Directive thresholds, specific contracts under a framework contract, whatever their value and contracts resulting from certain negotiated procedures without publication of a contract notice.

11.4. Bank account

Tenderers are advised that they will need to hold a bank account in the same currency as the currency indicated in the tender. For example, a bank account in Euros must be held for payments to be made by the Agency in Euros.

12. Tenders under €140,000

12.1. Procedure under €140,000

As indicated in 2. above, this document is primarily intended to give information on the tendering procedures for those tenders which have a value over the threshold of the Directive and which follow the **open** or **restricted** procedures. Tenders for goods and/or services with a value under €140,000 are normally conducted differently by using a negotiated procedure in accordance with the general **Financial Regulation**. For tenders in the range of €15,000 to €59,999 the Agency must consult at least three candidates and in the range of €60,000 to €139,999 at least five candidates. Below €15,000 only one candidate needs to be consulted.

12.2. Advertising of tenders under €140,000

Tenders up to €140,000 follow similar principles to those outlined in this document for the **open** and **restricted** procedures. They still require evaluation according to exclusion, selection and award criteria. However, advertising in the OJEU is not mandatory and evidence of fulfilment of exclusion and selection criteria might not be required, according to the Agency's analysis of risks.

The Agency is obliged to publish an *ex ante* advertisement for at least two weeks for planned procurements with a value exceeding €15,000 and below €140,000 on its external webpage:

<https://www.ema.europa.eu/en/about-us/procurement#calls-for-tender-worth-€15,000---€140,000-section>

Should an economic operator be interested in submitting a tender as a result of this *ex ante* advertisement, it should contact the person indicated in the relevant advertisement.

Since procurement procedures in this contract range may be organised at short notice, it is not possible to publish a plan of all such procurements foreseen in the coming year. Should economic operators wish to receive the latest information on procurements in this range of values, they should send an e-mail to: contracts@ema.europa.eu and provide the following information:

- the name and address of the company or individual,
- the business area in which it is involved,
- the nature of the procurements which may be of interest.

The Agency will endeavour to advise as far as possible of the number and type of contracts envisaged, a general indication of their purpose and the indicative time schedule for the procurement procedure(s), if known.

Please note that the Agency is unable to offer a mailing list service or a notification of the launch of individual procurement procedures.

13. Negotiated procedures

As indicated in 2. above, this document is primarily intended to give information on the procurement procedures for those tenders which have a value over the threshold of the Directive and which follow the **open** or **restricted** procedures. The Agency may also conduct negotiated procedures in accordance with the legal bases for such procedures as set out in Articles 11 and 12 of Annex I to the general Financial Regulation¹⁶.

14. Access to documents

The Agency is subject to Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents as applicable to the Agency pursuant to article 73 of Regulation (EC) 726/2004 as amended. This Regulation sets out provisions which guarantee openness and transparency of the activities of European institutions, whilst also ensuring the protection of certain public and private interests.

END

¹⁶ 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
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046>

References

At the time of writing, the websites listed below contained information mentioned in the present document or relevant for its purposes:

Name or owner of website	URL	Main information to be found
European Medicines Agency (the Agency)	https://www.ema.europa.eu/en/about-us/procurement	Information on ongoing calls for tenders. Tendering specifications available for downloading in the case of open procedures.
European Medicines Agency (the Agency)	https://www.ema.europa.eu/	General information on the Agency and its work. Documents published by the Agency.
Europa	http://europa.eu	List of EU Institutions, Agencies and other Bodies
European Commission	https://ec.europa.eu/info/about-european-union/principles-and-values/use-languages_en	Official EU languages
European Commission – Contact page	https://ec.europa.eu/commission/index_en	General contact information. Code of Good Administrative Behaviour. General information about the European Commission.
SIMAP	http://simap.ted.europa.eu/	Public Procurement Directive. Comprehensive information about procurement in Europe.
TED (Tenders Electronic Daily)	https://ted.europa.eu/TED/main/HomePage.do	Notices published in the Official Journal of the European Union.
e-Tendering website	https://etendering.ted.europa.eu/general/page.html?name=home	Economic operators can view and download all procurement documents for certain tenders over the value of the Public Procurement Directive.
EUR-LEX	https://eur-lex.europa.eu/homepage.html	European Union law.
European Court of Justice	https://curia.europa.eu/jcms/jcms/index.html	Case law of the Court of Justice of the European Union.
European Ombudsman	https://www.ombudsman.europa.eu/en/home	European Ombudsman's decisions.

Annex II

Sample exclusion criteria declaration upon honour and detail of supporting documentation required

Declaration of honour on exclusion criteria and selection criteria

Procedure reference number:

Procedure title:

A. DECLARATION ON HONOUR ON EXCLUSION CRITERIA

The undersigned insert name of signatory

<i>(only for natural persons)</i> representing himself or herself	<i>(only for legal persons)</i> representing the following legal person:
ID or passport number:	Full official name:
(‘the person’)	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 EMA, 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;	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>

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 credibility 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;	<input type="checkbox"/>	<input type="checkbox"/>
(ii) entering into agreement with other persons with the aim of distorting competition;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) violating intellectual property rights;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>
(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, or corruption as defined in other applicable laws;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;	<input type="checkbox"/>	<input type="checkbox"/>
(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;	<input type="checkbox"/>	<input type="checkbox"/>
(v) terrorist offences or offences related to terrorist activities as well as of inciting, aiding, abetting or attempting to commit such offences as defined in Articles 3, 14 and Title III of Directive (EU) 2017/541 of the European Parliament and of the Council of 15 March 2017 on combating terrorism;	<input type="checkbox"/>	<input type="checkbox"/>
(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;	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>
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;	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>
h) (<i>only for legal persons</i>) it has been established by a final judgment or final administrative decision that the person has been created with the intent referred to	<input type="checkbox"/>	<input type="checkbox"/>

in point (g).		
(2) declares that, for the situations referred to in points (1) (c) to (1) (h) above, in the absence of a final judgement or a final administrative decision, the person is ¹⁷ :	YES	NO
i. subject to facts established in the context of audits or investigations carried out by the European Public Prosecutor's Office, the Court of Auditors, 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;	<input type="checkbox"/>	<input type="checkbox"/>
ii. subject to 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	<input type="checkbox"/>	<input type="checkbox"/>
iii. subject to facts referred to in decisions of entities or persons being entrusted with EU budget implementation tasks;	<input type="checkbox"/>	<input type="checkbox"/>
iv. subject to information transmitted by Member States implementing Union funds;	<input type="checkbox"/>	<input type="checkbox"/>
v. subject to 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;	<input type="checkbox"/>	<input type="checkbox"/>
vi. informed, by any means, that it is subject to an investigation by the European Anti-Fraud office (OLAF): either because it has been given the opportunity to comment on facts concerning it by OLAF, or it has been subject to on-the-spot checks by OLAF in the course of an investigation, or it has been notified of the opening, the closure or of any circumstance related to an investigation of the OLAF concerning it.	<input type="checkbox"/>	<input type="checkbox"/>

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 when the tenderer/candidate is a natural person, Member States or a local authority

(3) declares that a natural or legal person who is a member of the administrative, management or supervisory body of the person, or who has powers of representation, decision or control with regard to the 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 defined by point 6 of Article 3 of Directive (EU) No 2015/849) is in one of the following situations:	YES	NO	N/A
Situation (1)(c) above (grave professional misconduct)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (1)(d) above (fraud, corruption or other criminal offence)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (1)(e) above (significant deficiencies in performance of a contract)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (1)(f) above (irregularity)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (1)(g) above (creation of an entity with the intent to circumvent legal obligations)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (1)(h) above (person created with the intent to circumvent legal obligations)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

¹⁷ The declaration under this point (2) is voluntary and it cannot have adverse legal effect on the economic operator until the conditions of Article 141(1) (a) FR are met.

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

Not applicable when the tenderer or candidate is a natural person, a Member State, a local authority or legal persons with limited liability

(4) declares that a natural or legal person that assumes unlimited liability for the debts of the person is in one of the following situations:	YES	NO	N/A
Situation (a) above (bankruptcy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (b) above (breach in payment of taxes or social security contributions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

IV – Grounds for rejection from this procedure

(5) declares that the 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.	<input type="checkbox"/>	<input type="checkbox"/>

V – Remedial measures

If the person declares one of the situations of exclusion listed above, it must indicate remedial measures it has taken to remedy the exclusion situation, in order to allow the authorising officer to determine whether such measures are sufficient to demonstrate 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 (1) (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 and appropriate evidence that none of those persons are in one of the exclusion situations referred to in (1) (c) to (f).

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 points (1): (a), (c), (d), (f), (g) and (h) above, a recent extract from the judicial record 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 (1) (a), (b), recent certificates issued by the competent authorities of the country of establishment. 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 of establishment, 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 EMA. The documents must have been issued no more than one year before the date of the request by the EMA 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

The person is not required to submit the evidence if it can be accessed on a national database free of charge.

The signatory declares that the following internet address of the database/identification data provide access to the evidence required.

Internet address of the database	Identification data of the document

B. DECLARATION ON HONOUR ON SELECTION CRITERIA

I – Selection criteria

Selection criteria applicable to the tenderer/candidate as a whole-consolidated assessment

(to be filled ONLY by the sole candidate/tenderer or the group leader in case of a joint tender)

The person, being a sole candidate/tenderer/the group leader of a joint tender/request to participate, submitting a request to participate/tender for the above procedure, declares that:

the candidate/tenderer, including all members of the group in case of joint tender/request to participate, subcontractors and entities on whose capacity the tenderer intends to rely upon, if applicable:	YES	NO
(a) fulfils all the selection criteria for which a consolidated assessment will be made as provided in the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>
(b) is not subject to conflicting interests which may negatively affect the contract performance.	<input type="checkbox"/>	<input type="checkbox"/>

In case of a procedure with lots the above statements apply to the lot(s) for which the request to participate/tender is submitted.

Option below to be inserted when applicable in accordance with the procurement documents. The section below must be deleted if there are no selection criteria applicable individually. If there are such criteria, the table must be adapted to the criteria indicated in the tender specifications.

Selection criteria applicable individually to the involved entities of the tenderer/candidate- individual assessment

(to be filled individually by all members in case of a joint tender/request to participate and subcontractors)

The person, being a member of a joint tender/request to participate or a subcontractor, submitting a request to participate/tender for the above procedure, declares that:

the above-mentioned person complies with the selection criteria applicable to it individually:	YES	NO	N/A
(a) has the legal and regulatory capacity to pursue the professional activity needed for performing the contract as required in section [<i>insert</i>] of the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) fulfills the applicable economic and financial criteria indicated in section [<i>insert</i>] of the tender specifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) fulfills the applicable technical and professional criteria indicated in section [<i>insert</i>] of the tender specifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(d) is not subject to conflicting interests which may negatively affect the contract performance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

II – Evidence upon request

The person must be able to provide the selection criteria supporting documents listed in the relevant sections of the tender specifications.

Where the evidence is not required to be provided with the request to participate/tender, the person is invited to prepare in advance the documents related to the evidence, since the contracting authority may request to provide these in a short deadline.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure of the same contracting authority . 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

The person is not required to submit the evidence if it can be accessed on a national database free of charge.

The signatory declares that the following internet address of the database/identification data provide access to the evidence required.

Internet address of the database	Identification data of the document

C. DECLARATION ON HONOUR ON ESTABLISHED DEBT TO THE UNION

(to be filled ONLY by the sole candidate/tenderer or the group leader in case of a joint tender)

The person, being a sole candidate/tenderer/the group leader of a joint tender/request to participate, submitting a request to participate/tender for the above procedure, declares that:

the candidate/tenderer, including each member of the group in case of joint tender/request to participate, subcontractors,	YES	NO
does not have an established debt to the Union.	<input type="checkbox"/>	<input type="checkbox"/>

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.

Date:

Signature of authorised representative:

(Print name):

Position in company:

Representing (name of tenderer):