



EUROPEAN COMMISSION  
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Directorate E- Modernisation of the Single Market

## **CALL FOR TENDERS**

**No 751/PP/GRO/IMA/19/1131/10885**

**MAPPING AND ASSESSMENT OF DEVELOPMENTS  
FOR SECTORAL PROFESSIONS UNDER  
DIRECTIVE 2005/36/EC:**

**LOT 1: THE PROFESSION OF DENTAL PRACTITIONER  
LOT 2: THE PROFESSION OF PHARMACIST**

**Open procedure**

**TENDER SPECIFICATIONS**

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## 1. TECHNICAL SPECIFICATIONS

The purpose of this Call for Tender is to commission studies on the following topic:

Mapping and assessment of developments for sectoral professions under Directive 2005/36/EC:

Lot 1: The profession of dental practitioner.

Lot 2: The profession of pharmacist.

Tenderers may submit tenders for both or for one of the lots.

### 1.1. Lot 1 – The profession of dental practitioners

#### *1.1.1. Description of tasks*

##### 1.1.1.1. Rationale and objectives

The purpose of this call for tender is to commission a study that would assist the European Commission in its review of the minimum training requirements for the profession of dental practitioners under Directive 2005/36/EC, as amended ("the Directive")<sup>1</sup>. The purpose of the review is for the Commission to assess whether there is a need to propose an adaptation of these minimum training requirements in order to take account of scientific and technical progress, and within the limits of the delegated powers granted to the Commission under the Directive in question.

While minimum training requirements for this profession have been harmonized at EU level, Member States retain the power to introduce additional requirements, should they consider it necessary. Since the minimum training requirements of the Directive have been set out more than 30 years ago, it is necessary for the Commission to proceed to a review of the current situation on the national level as regards the training requirements that are effectively imposed in the training of dental practitioners with a particular focus on requirements that go beyond the minima required under the Directive.

In that context, the study would, first of all, map the current national requirements in all EU and EFTA States (Iceland, Liechtenstein, Norway and Switzerland) with regard to the effective theoretical and clinical training of dental practitioners and the knowledge and skills that they should acquire by such training. Such mapping should particularly focus on and indicate any requirement which goes beyond or extends any of the minimum training requirements of the Directive. It should also consider whether these requirements reflect an adaptation to scientific and technical progress.

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<sup>1</sup> Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255 30.9.2005, p. 22), as amended; consolidated version: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1517331795984&uri=CELEX:02005L0036-20171201>.

To the extent necessary to explain relevant training developments in national contexts, the study shall also include an analysis of national health systems. The contractor is expected to take into account all relevant information and sources including existing work undertaken in the area.

Secondly, based on any commonalities in the national requirements of the Member States, the study should assess whether it would be appropriate for the EU to update the minimum training requirements laid down under point 5.3.1 of Annex V of the Directive and under Article 34(3) of the Directive, for which the Commission was granted delegated powers under Articles 21(6) and 34(2) of the Directive, and, if so, to what extent. The same applies for specialist dentists as to whether new specialisations could be added to Annex 5.3.3 to the Directive in line with Article 35(5) or whether the minimum duration of three years, as set out in Article 35(2) of the Directive, should be adapted.

In developing their suggestions in this respect, the contractor would also be required to organize a workshop and build a common understanding with the relevant national authorities and stakeholders on whether updates to the minimum training requirements under the Directive within the scope of the Commission's delegated powers might be appropriate and if so, to what extent.

Finally, the study shall also provide suggestions on possible updates to the Directive, that the contractor considers appropriate on the basis of his research, assessment and interaction with authorities and stakeholders, such suggestions being fully evidenced and substantiated. The contractor shall pay particular attention to the limits of the delegated powers of the Commission under the Directive, throughout the process.

### 1.1.1.2. Description of tasks

The contractor is expected to deliver the following tasks:

**Task (1) - Collection and presentation of data.** The contractor should collect data with regard to national rules in all EU and EFTA States concerning the effective theoretical and practical training as well as the knowledge and skills required from dental practitioners. Particular focus should be given to requirements that go beyond the minimum training requirements of the Directive and the justification given by the relevant bodies as to the reason for their imposition, in particular, whether the requirements reflect an adaptation to scientific and technical progress in the given area.

Data should be collected from all available sources, which should necessarily include: national law, representative sample of training institutions: universities/higher institutes or accreditation bodies (depending on whether or not the training content is organized/supervised at a central level in the given Member State), professional organisations, regulatory and supervisory authorities. A draft list of stakeholders that the contractor intends to contact should be included in the tender.

The methodology of data collection shall take into account the fact that the minimum training requirements concerning knowledge and skills under Article 34(3) of the Directive are outcome based while the minimum training requirements under point 5.3.1 of Annex V consist of a list of the training subjects/areas. Data and relevant justifications shall be presented both per country and in a comparative manner.

The Directive is not based on EU Qualification Frameworks (EQF), its levels and learning outcomes. The Directive groups various national education and training schemes into different levels established for the purpose of the operation of the Directive and lays down the minimum training requirements without reference to EQF. Thus, it is important to stress that the design and conduct of the research by the contractor and the presentation of any possible proposals for an update of the Directive would have to be based on the way the minimum training requirements are dealt with and presented in the Directive, irrespective of the EQF level accorded in the Member State concerned.

For specialist dentists new existing specialisations should be identified in the Member States and the duration of already existing specialisations should be scrutinised in the light of the current existing three year minimum duration.

When defining the methodology of data collection, the need to contact more than one stakeholder per in certain Member States should be taken into account to ensure completeness of data collected. This may be the case where for example there are regional differences in regulation or where the universities have large scope of manoeuvre with regard to defining curricula.

**Task (2) - Comparative assessment of data.** On the basis of the raw data, developments in Member States and commonalities on requirements (specifically on those going beyond the minimum training requirements of the Directive), should be assessed and explained taking specifically into account justifications and relations with generally acknowledged scientific and technical progress.

The goal of the assessment would be to establish whether it is feasible and advisable to update the minimum training requirements laid down in point 5.3.1 of Annex V to the Directive and in Article 34(3) of the Directive, on the basis of the respective delegated powers laid down in Articles 21(6) and 34(2) of the Directive, and Article 35(2) and (5) for specialist dentists, on the basis of the respective delegated powers laid down in Article 57c of the Directive.

The contractor shall also consider any relevant pre-existing work, study or proposal already made in that area.

Objective collection and assessment of data is a requirement of capital importance before the tenderer reaches a common understanding on the views of relevant stakeholders and draws final conclusions.

**Task (3) - Presentation of the results of data collection/assessment and discussion with the relevant stakeholders.** In particular, a common understanding should be built with the relevant stakeholders on whether it would be appropriate and feasible to update the minimum training requirements with regard to dental practitioners given the limits of the delegated powers of the Commission under the Directive, and if so, to what extent.

To this end the contractor shall organise a workshop for approximately 65 participants (invitations should be sent at least to regulatory bodies, professional organisations (EU/EFTA and national level), and academia in all EU Member States and EFTA States and to the representatives of the Commission). Participation should be free of charge and the workshop should be web-streamed. The contractor shall be in charge of logistics (invitation, programme, identification of speakers and participants, venue and catering, evaluation). Costs of 6 to 10 speakers should be included in the

price. The list of participants to be invited, the agenda of the workshop, presentation and discussion paper are subject to prior approval of the Commission. Duration of the workshop: one day.

Furthermore, the contractor shall deliver a presentation to the Group of Coordinators for Directive 2005/36/EC<sup>2</sup> in Brussels and encourage feedback. The Commission will organise the meeting and venue. The cost of participation of the contractor's representative(s) delivering the presentation shall be included in the price. Presentation is subject to prior approval by the Commission. Duration: half a day.

**Task (4) - Drafting of the final study** on the basis of further reflection on the outcomes of the Tasks (1) to (3). If the conclusions of the study would support a recommendation for amendments to the minimum training requirements under the Directive, the proposal for an update should be presented in such a way that it could easily be used by the Commission to proceed to the actual update of the minimum training requirements by means of a Delegated Act, if the Commission deems it appropriate.

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to the Directive 2014/24/EU.

### *1.1.2. Background*

Directive 2005/36/EC, as amended, lays down harmonized minimum training requirements for seven professions (so-called sectorial professions) including dental practitioners. The requirements in question have been initially developed more than 30 years ago, in the context of profession specific Directives, which have subsequently been codified by Directive 2005/36/EC.

With regard to the profession of dental practitioner, the Directive defines the relevant minimum training requirements in its Article 34. These include the minimum length and number of hours to be covered by the theoretical and clinical training (Article 34(2)) and the minimum knowledge and skills that the dental practitioners should have acquired during the training (Article 34(3)). Article 34(2) subparagraph 2 provides for a reference to point 5.3.1 of Annex V where the minimum training programme is set out. For specialist dentists, Article 35(2) of the Directive solely specifies that dental specialisations should be of a minimum duration of three years.

These harmonised minimum training requirements are the basis for the automatic recognition of the relevant professional qualifications across the EU, such recognition being considered as one of the main achievements in the field of cross-border professional recognition of qualifications in the EU.

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<sup>2</sup> The Group of Coordinators established under Commission Decision 2007/172/EC of 19 March 2007 setting up the group of coordinators for the recognition of professional qualifications (OJ L 79, 20.3.2007, p. 38)

It has to be noted that, contrary to dental practitioners, for specialist dentists the Member States are not obliged to participate in the automatic recognition system.<sup>3</sup>

While the training requirements have been to a certain extent reviewed with the last revision of the Directive (through Directive 2013/55/EU<sup>4</sup>), no substantial changes have been made either to the training programmes or to minimum skills and knowledge of professionals. Instead, Directive 2013/55/EU has provided delegated powers to the Commission to introduce possible updates, if necessary, at a later stage. With regard to the profession of dental practitioners, the Commission has been granted delegated powers to update only certain minimum training requirements:

Firstly, under Article 21(6) the Commission has been empowered to adopt delegated acts to update the knowledge and skills referred to in Article 34(3) of the Directive.

Current wording of Article 34(3) of the Directive:

*3. Basic dental training shall provide an assurance that the person in question has acquired the following knowledge and skills:*

*(a) adequate knowledge of the sciences on which dentistry is based and a good understanding of scientific methods, including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data;*

*(b) adequate knowledge of the constitution, physiology and behaviour of healthy and sick persons as well as the influence of the natural and social environment on the state of health of the human being, in so far as these factors affect dentistry;*

*(c) adequate knowledge of the structure and function of the teeth, mouth, jaws and associated tissues, both healthy and diseased, and their relationship to the general state of health and to the physical and social well-being of the patient;*

*(d) adequate knowledge of clinical disciplines and methods, providing the dentist with a coherent picture of anomalies, lesions and diseases of the teeth, mouth, jaws and associated tissues and of preventive, diagnostic and therapeutic dentistry;*

*(e) suitable clinical experience under appropriate supervision.*

*This training shall provide him with the skills necessary for carrying out all activities involving the prevention, diagnosis and treatment of anomalies and diseases of the teeth, mouth, jaws and associated tissues.*

Secondly, under Article 34(2) of the Directive the Commission has been empowered to adopt delegated acts concerning amendments to the list set out in point 5.3.1 of Annex V (minimum training programme).

Current list set out in point 5.3.1 of Annex V to the Directive:

### **5.3.1 Study programme for dental practitioners**

*The programme of studies leading to evidence of formal qualifications in dentistry shall include at least the following subjects. One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.*

#### **A. Basic subjects**

- Chemistry
- Physics
- Biology

#### **B. Medico-biological subjects and general medical subjects**

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<sup>3</sup> See i.e. Austria, Croatia, Latvia, Luxembourg and Spain who do not have an entry for oral surgery or orthodontics in Annex 5.3.3.

<sup>4</sup> Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ( ‘the IMI Regulation’ ) OJ L 354, 28.12.2013, p. 132–170



- *Anatomy*
- *Embryology*
- *Histology, including cytology*
- *Physiology*
- *Biochemistry (or physiological chemistry)*
- *Pathological anatomy*
- *General pathology*
- *Pharmacology*
- *Microbiology*
- *Hygiene*
- *Preventive medicine and epidemiology*
- *Radiology*
- *Physiotherapy*
- *General surgery*
- *General medicine, including paediatrics*
- *Oto-rhino-laryngology*
- *Dermato-venereology*
- *General psychology — psychopathology — neuropathology*
- *Anaesthetics*

### *C. Subjects directly related to dentistry*

- *Prosthodontics*
- *Dental materials and equipment*
- *Conservative dentistry*
- *Preventive dentistry*
- *Anaesthetics and sedation*
- *Special surgery*
- *Special pathology*
- *Clinical practice*
- *Paedodontics*
- *Orthodontics*
- *Periodontics*
- *Dental radiology*
- *Dental occlusion and function of the jaw*
- *Professional organisation, ethics and legislation*
- *Social aspects of dental practice*

Both in case of delegated powers granted under Article 34(2) and under Article 21(6), the purpose of possible amendments shall be the adaptation of the minimum training requirements to scientific and technical progress. Such updates shall not entail an amendment of existing essential legislative principles in Member States regarding the structure of professions as regards training and conditions of access by natural persons. Such amendments shall respect the responsibility of the Member States for the organisation of education systems, as set out in Article 165(1) of the Treaty on the Functioning of the European Union (TFEU).

Thirdly, for specialist dentists, under Article 35(4) of the Directive, the Commission has been empowered to adopt delegated acts to update the minimum period of training referred to in Article 35(2) of the Directive to scientific and technical progress. Moreover, Article 35(5) of the Directive empowers the Commission to adopt delegated acts to include new dental specialties in Annex 5.3.3. to the Directive.

Current wording of Article 35 of the Directive:

## 2. Contractual conditions

2. *Specialist dental training shall comprise theoretical and practical instruction in a university centre, in a treatment teaching and research centre or, where appropriate, in a health establishment approved for that purpose by the competent authorities or bodies.*

*Full-time specialist dental courses shall be of a minimum of three years' duration and shall be supervised by the competent authorities or bodies. They shall involve the personal participation of the dental practitioner training to be a specialist in the activity and in the responsibilities of the establishment concerned.*

4. *The Commission shall be empowered to adopt delegated acts in accordance with Article 57c concerning the adaptation of the minimum period of training referred to in paragraph 2 to scientific and technical progress.*

5. *In order to take due account of changes in national legislation, and with a view to updating this Directive, the Commission shall be empowered to adopt delegated acts in accordance with Article 57c concerning the inclusion in point 5.3.3 of Annex V of new dental specialties common to at least two-fifths of the Member States.*

In the context of the last revision of the Directive, national authorities, academic institutions and professional organisations indicated that the sectorial professions have significantly evolved since their minimum training requirements were harmonised at European level.

In its 2011 Green Paper (COM(2011)367 final) on the modernisation of the Professional Qualifications Directive<sup>5</sup> the Commission also acknowledged that a possible modernisation of these minimum training requirements needs to be considered in different phases.

Having the above in mind, the Commission decided to tender a study that would provide for the necessary background information and assessment to assist the Commission in taking an informed decision on whether amendments to the Directive with regard to the minimum training requirements would be appropriate and if so, to what extent. Such possible amendments may consist in adding new minimum requirements and/or in modifying the existing minimum training requirements in the Directive.

Based upon the current pilot study on the profession of nurse responsible for general care, the Commission decided to continue with the profession of dental practitioner.

### *1.1.3. Reports and documents*

The Contractor is to provide the required reports and documents in accordance with the conditions of the standard service contract.

The contractor must deliver the study and other deliverables, as indicated below.

Each deliverable shall provide well-structured information using clear language and, where appropriate, tables and graphs, to present data in a clear manner. Each deliverable shall be written in correct English and verified by a person with a native or equivalent knowledge of the English language. All deliverables along with raw data that served as a basis for the assessment shall be submitted in electronic format compatible with Word/Excel.

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<sup>5</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0367:FIN:en:PDF>

The relevant tasks should be accomplished in line with the timing indicated in the table below.

**The presentations of the findings to the public and in particular, the conclusions with regard to the possible amendments to the Directive, are subject to prior approval of the Commission.**

Time-line	Meetings	Reports	Approval of reports	Payments
Contract signature				30% pre-financing
M1	Kick-off meeting in Brussels			
M4	Meeting with the Commission to present the work completed so far and discuss the way forward	Submission of data collected and presented per country and in a comparative manner		
M8		Submission the draft study to the Commission and the drafts: discussion paper, presentations and agenda including potential speakers for the workshop		
M10			Comments from the Commission /approval of the drafts	Invoicing 20% interim payment subject to approval of the draft study and other above-mentioned documents
M11	Workshop			
M11	Presentation to GoC			
M11	Meeting with the Commission to discuss the outcomes of the workshop/feedback from GoC and the necessity to correct the draft study			
M12	Submission of the feedback report to the		Comments from the Commission	

## 2. Contractual conditions

	Commission		/approval of the feedback report	
M14		Submission of draft final study including proposal for amendments if applicable		
M15			Further comments from the Commission /approval of the draft final study	
M15	Submission of the revised final study to the Commission in case the Commission had comments in M15			
M15	Final meeting in Brussels			Invoicing of the remaining 50% of the price of the contract subject to approval of the final study

### 1.1.3.1. Documents for the kick-off meeting

The kick-off meeting shall take place within 3 weeks after the signature of the contract. The objective of the meeting is to ensure the mutual understanding of the contractor's work plan and timeline for carrying out the tasks described in the terms of reference.

In this meeting, the contractor shall provide the Commission with the detailed description of the contractor's work plan and the timeline for carrying out the tasks.

### 1.1.3.2. Minutes

The contractor shall draft the minutes of the meetings with the Commission and shall submit them for comments/approval the Commission no later than 1 week after each meeting.

### 1.1.3.3. Data collected and presented per EU/EFTA country and in a comparative manner

### 1.1.3.4. Draft study

The draft study should contain:

- an explanation of methodology applied to data collection and its assessment and clearly stated data sources;
- a state of play for each of the countries concerned with regard to theoretical and practical training (point 5.3.1 of Annex V to the Directive) as well as knowledge and skills (Article 34(3) of the Directive);

- an analysis of each national health system to the extent necessary for the explanation of the relevant developments in its context;
- an assessment of convergence of the developments in the EU/EFTA countries;
- preliminary assessment on whether it would be recommended to update the minimum training requirements for dental practitioners and specialist dentists laid down in the Directive and to what extent.

### 1.1.3.5. Discussion paper for the workshop

Discussion paper based on the draft study should be of maximum 10 pages and should cover the mapping, the comparative assessment, and the conclusions/proposal, if applicable.

### 1.1.3.6. Agenda and presentations for the workshop and to the Group of Coordinators

Presentations based on the draft study should cover the mapping, the comparative assessment and the conclusions.

### 1.1.3.7. Feedback paper from workshop

The paper of maximum 5 pages shall summarise the key learning elements, including pertinent comments/positions of different stakeholders and shall include recommendations for further research/redrafting of the study if relevant.

### 1.1.3.8. Final study (and draft final study)

The final study shall be composed of all the elements of the draft study and must also include:

- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;
- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:  
“The information and views set out in this study are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission’s behalf may be held responsible for the use which may be made of the information contained therein.”
- information about the outcomes of the workshop and views of the relevant stakeholders on possible amendments to the Directive;
- conclusions on whether it would be recommended to update the minimum training requirements laid down in the Directive and to what extent. The methodology applied to this assessment should be explained;
- if the conclusion is that amendments would be appropriate, the report shall contain a proposal of amendments presented in such a way that the text could be easily used, if the Commission deems it appropriate, in the future delegated act.

The possibility to amend the Directive is subject to certain conditions laid down in Articles 21(6) and 34(2) of the Directive. These conditions should obviously be taken into account when assessing whether it would be appropriate to amend the Directive and in formulation of possible proposals for amendments.

Such updates shall not entail an amendment of existing essential legislative principles in Member States regarding the structure of professions as regards training and conditions of access by natural persons. Such updates shall respect the responsibility of the Member States for the organisation of education systems, as set out in Article 165(1) of the Treaty on the Functioning of the European Union (TFEU).

### 1.1.3.8.1. Publishable executive summary

The publishable executive summary must be provided both in English and French and must include:

- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:

“The information and views set out in this study are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission’s behalf may be held responsible for the use which may be made of the information contained therein.”

### 1.1.3.8.2. Requirements for publication on Internet

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on the Commission policy on accessibility for information providers, see: [http://ec.europa.eu/ipg/standards/accessibility/index\\_en.htm](http://ec.europa.eu/ipg/standards/accessibility/index_en.htm)

For the publishable versions of the study, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: <http://www.w3.org/WAI/>.

### 1.1.3.8.3. Graphic requirements

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at:

[http://ec.europa.eu/dgs/communication/services/visual\\_identity/index\\_en.htm](http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm)

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.

## 1.2. Lot 2 – The profession of pharmacist

### 1.2.1. Description of tasks

#### 1.2.1.1. Rationale and objectives

The purpose of this call for tender is to commission a study that would assist the European Commission in its assessment whether to propose an adaptation of the minimum training requirements for the profession of pharmacist under Directive 2005/36/EC, as amended ("the Directive")<sup>6</sup>, in order to take account of scientific and technical progress, within the limits of the delegated powers granted to the Commission under this Directive.

While minimum training requirements for this profession have been harmonized on EU level, Member States retain the power to introduce additional requirements, should they consider it necessary. Since certain minimum training requirements of the Directive have been set out more than 30 years ago, it is necessary for the Commission to proceed to a review of the current situation on the national level as regards the training requirements that are effectively imposed in the training of pharmacists with a particular focus on requirements that go beyond the minima required under the Directive.

In that context, the study would, first of all, map the current national requirements in all EU and EFTA States (Iceland, Liechtenstein, Norway and Switzerland) with regard to the subjects covered by the course of training of pharmacists and the knowledge and skills that they should acquire by such training. Such mapping should particularly focus on and indicate any requirement which goes beyond or extends any of the minimum training requirements of the Directive. It should also consider whether these requirements reflect an adaptation to scientific and technical progress, including the evolution of pharmacological practice.

To the extent necessary to explain relevant training developments in national contexts, the study shall also include an analysis of national health systems. The contractor is expected to take into account all relevant information and sources including existing work undertaken in the area.

Secondly, based on any commonalities in the national requirements of the Member States, the study should assess whether it would be appropriate for the EU to update the minimum training requirements laid down under point 5.6.1 of Annex V of the Directive and under Article 44(3) of the Directive, for which the Commission was granted delegated powers under Articles 44(2) and 21(6) of the Directive, respectively, and, if so, to what extent.

In developing their suggestions in this respect, the contractor would also be required to organize a workshop and build a common understanding with the relevant national authorities and

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<sup>6</sup> Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255 30.9.2005, p. 22), as amended; consolidated version: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1517331795984&uri=CELEX:02005L0036-20171201>

stakeholders on whether updates to the minimum training requirements under the Directive within the scope of the Commission's delegated powers might be appropriate and if so, to what extent.

Finally, the study shall also provide suggestions on possible updates to the Directive, that the contractor considers appropriate on the basis of his research, assessment and interaction with authorities and stakeholders, such suggestions being fully evidenced and substantiated. The contractor shall pay particular attention to the limits of the delegated powers of the Commission under the Directive, throughout the process.

### 1.2.1.2. Description of tasks

The contractor is expected to deliver the following tasks:

**Task (1) - Collection and presentation of data.** The contractor should collect data with regard to national rules in all EU and EFTA States concerning the subjects covered by the course of training as well as the knowledge and skills required from graduates. Particular focus should be given to requirements that go beyond the minimum training requirements of the Directive and the justification given by the relevant bodies as to the reason for their imposition, in particular, whether the requirements reflect an adaptation to scientific and technical progress in the given area.

Data should be collected from all available sources, which should necessarily include: national law, representative sample of training institutions: universities/vocational schools or accreditation bodies (depending on whether or not the training content is organized/supervised at a central level in the given Member State), professional organisations, regulatory and supervisory authorities. A draft list of stakeholders that the contractor intends to contact should be included in the tender.

The methodology of data collection shall take into account the fact that the minimum training requirements concerning knowledge and skills under Article 44(3) of the Directive are outcome based while the minimum training requirements under point 5.6.1 of Annex V consist of a list of the training subjects/areas. Data and relevant justifications shall be presented both per country and in a comparative manner.

The Directive is not based on EU Qualification Frameworks (EQF), its levels and learning outcomes. The Directive groups various national education and training schemes into different levels established for the purpose of the operation of the Directive and lays down the minimum training requirements without reference to EQF. Thus, it is important to stress that the design and conduct of the research by the contractor and the presentation of any possible proposals for an update of the Directive would have to be based on the way the minimum training requirements are dealt with and presented in the Directive, irrespective of the EQF level accorded in the Member State concerned.

When defining the methodology of data collection, the need to contact more than one stakeholder per in certain Member States should be taken into account to ensure completeness of data collected. This may be the case where for example there are regional differences in regulation or where the universities have large scope of manoeuvre with regard to defining curricula.

**Task (2) - Comparative assessment of data.** On the basis of the raw data, developments in Member States and commonalities on requirements (specifically on those going beyond the minimum training requirements of the Directive), should be assessed and explained taking



specifically into account justifications and relations with generally acknowledged scientific and technical progress.

The goal of the assessment would be to establish whether it is feasible and advisable to update the minimum training requirements laid down in point 5.6.1 of Annex V to the Directive and in Article 44(3) of the Directive, on the basis of the respective delegated powers laid down in Articles 44(2) and 21(6) of the Directive.

The contractor shall also consider any relevant pre-existing work, study or proposal already made in that area.

Objective collection and assessment of data is a requirement of capital importance before the tenderer reaches a common understanding on the views of relevant stakeholders and draws final conclusions.

**Task (3) - Presentation of the results of data collection/assessment and discussion with the relevant stakeholders.** In particular, a common understanding should be built with the relevant stakeholders on whether it would be appropriate and feasible to update the minimum training requirements with regard to pharmacists given the limits of the delegated powers of the Commission under the Directive, and if so, to what extent.

To this end the contractor shall organise a workshop for approximately 65 participants (invitations should be sent at least to regulatory bodies, professional organisations (EU/EFTA and national level), and academia in all EU Member States and EFTA States and to the representatives of the Commission). Participation should be free of charge and the workshop should be web-streamed. The contractor shall be in charge of logistics (invitation, programme, identification of speakers and participants, venue and catering, evaluation). Costs of 6 to 10 speakers should be included in the price. The list of participants to be invited, the agenda of the workshop, presentation and discussion paper are subject to prior approval of the Commission. Duration of the workshop: one day.

Furthermore, the contractor shall deliver a presentation to the Group of Coordinators for Directive 2005/36/EC<sup>7</sup> in Brussels and encourage feedback. The Commission will organise the meeting and venue. The cost of participation of the contractor's representative(s) delivering the presentation shall be included in the price. Presentation is subject to prior approval by the Commission. Duration: half a day.

**Task (4) - Drafting of the final study** on the basis of further reflection on the outcomes of the Tasks (1) to (3). If the conclusions of the study would support a recommendation for amendments to the minimum training requirements under the Directive, the proposal for an update should be presented in such a way that it could easily be used by the Commission to proceed to the actual update of the minimum training requirements by means of a Delegated Act, if the Commission deems it appropriate.

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<sup>7</sup> the Group of Coordinators established under Commission Decision 2007/172/EC of 19 March 2007 setting up the group of coordinators for the recognition of professional qualifications (OJ L 79, 20.3.2007, p. 38)

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to the Directive 2014/24/EU.

### 1.2.2. Background

Directive 2005/36/EC, as amended, lays down harmonized minimum training requirements for seven professions (so-called sectorial professions) including pharmacists. The requirements in question have been initially developed more than 30 years ago, in the context of profession specific Directives, which have subsequently been codified by Directive 2005/36/EC.

With regard to the profession of pharmacist, the Directive defines the relevant minimum training requirements in its Article 44. These include conditions for the admission to the training (Article 44(1)), the minimum length of the training as well as of the traineeship (Article 44(2) a) and b), minimum knowledge and skills that should be acquired during the training (Article 44(3)). The third subparagraph of Article 44(2) provides for a reference to point 5.6.1 of Annex V to the Directive where the minimum training programme is set out.

These harmonised minimum training requirements are the basis for the automatic recognition of the relevant professional qualifications across the EU, such recognition being considered as one of the main achievements in the field of cross-border professional recognition of qualifications in the EU.

While the training requirements have been to a certain extent reviewed with the last revision of the Directive (through Directive 2013/55/EU<sup>8</sup>), no substantial changes have been made either to the training programmes or to minimum skills and knowledge of professionals. Instead, Directive 2013/55/EU has provided delegated powers to the Commission to introduce possible updates, if necessary, at a later stage. With regard to the profession of pharmacist, the Commission has been granted delegated powers to update only certain minimum training requirements:

Firstly, under Article 21(6) the Commission has been empowered to adopt delegated acts to update the knowledge and skills referred to in Article 44(3) of the Directive.

Current wording of Article 44(3) of the Directive:

*3. Training for pharmacists shall provide an assurance that the person concerned has acquired the following knowledge and skills:*

- (a) adequate knowledge of medicines and the substances used in the manufacture of medicines;*
- (b) adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products;*
- (c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products;*
- (d) adequate knowledge to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge;*

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<sup>8</sup> Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ( ‘the IMI Regulation’ ) OJ L 354, 28.12.2013, p. 132–170

*(e) adequate knowledge of the legal and other requirements associated with the pursuit of pharmacy.*

Secondly, under the third subparagraph of Article 44(2) of the Directive the Commission has been empowered to adopt delegated acts concerning amendments to the list set out in point 5.6.1 of Annex V (minimum training programme).

Current list set out in point 5.6.1 of Annex V to the Directive:

### *5.6.1. Course of training for pharmacists*

- *Plant and animal biology*
- *Physics*
- *General and inorganic chemistry*
- *Organic chemistry*
- *Analytical chemistry*
- *Pharmaceutical chemistry, including analysis of medicinal products*
- *General and applied biochemistry (medical)*
- *Anatomy and physiology; medical terminology*
- *Microbiology*
- *Pharmacology and pharmacotherapy*
- *Pharmaceutical technology*
- *Toxicology*
- *Pharmacognosy*
- *Legislation and, where appropriate, professional ethics.*

*The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.*

Both in case of delegated powers granted under Article 44(2) and under Article 21(6), the purpose of possible amendments shall be the adaptation of the minimum training requirements to scientific and technical progress. Such updates shall not entail an amendment of existing essential legislative principles in Member States regarding the structure of professions as regards training and conditions of access by natural persons. Such amendments shall respect the responsibility of the Member States for the organisation of education systems, as set out in Article 165(1) of the Treaty on the Functioning of the European Union (TFEU).

In the context of the last revision of the Directive, national authorities, academic institutions and professional organisations indicated that the sectorial professions have significantly evolved since their minimum training requirements were harmonised at European level.

In its 2011 Green Paper (COM(2011)367 final) on the modernisation of the Professional Qualifications Directive<sup>9</sup> the Commission also acknowledged that a possible modernisation of these minimum training requirements needs to be considered in different phases.

Having the above in mind, the Commission decided to tender a study that would provide for the necessary background information and assessment to assist the Commission in taking an informed decision on whether amendments to the Directive with regard to the minimum training requirements for the profession of pharmacist would be appropriate and if so, to what extent. Such possible

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<sup>9</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0367:FIN:en:PDF>

amendments may consist in adding new minimum requirements and/or in modifying the existing minimum training requirements in the Directive.

Based upon the current pilot study on the profession of nurse responsible for general care, the Commission decided to continue with the profession of pharmacist.

**1.2.3. Reports and documents**

The Contractor is to provide the required reports and documents in accordance with the conditions of the standard service contract.

The contractor must deliver the study and other deliverables, as indicated below.

Each deliverable shall provide well-structured information using clear language and, where appropriate, tables and graphs, to present data in a clear manner. Each deliverable shall be written in correct English and verified by a person with a native or equivalent knowledge of the English language. All deliverables along with raw data that served as a basis for the assessment shall be submitted in electronic format compatible with Word/Excel.

The relevant tasks should be accomplished in line with the timing indicated in the table below.

**The presentations of the findings to the public and in particular, the conclusions with regard to the possible amendments to the Directive, are subject to prior approval of the Commission.**

Time-line	Meetings	Reports	Approval of reports	Payments
Contract signature				30% pre-financing
M1	Kick-off meeting in Brussels			
M4	Meeting with the Commission to present the work completed so far and discuss the way forward	Submission of data collected and presented per country and in a comparative manner		
M8		Submission the draft study to the Commission and the drafts: discussion paper, presentations and agenda including potential speakers for the workshop		

## 2. Contractual conditions

M10			Comments from the Commission /approval of the drafts	Invoicing 20% interim payment subject to approval of the draft study and other above-mentioned documents
M11	Workshop			
M11	Presentation to GoC			
M11	Meeting with the Commission to discuss the outcomes of the workshop/feedback from GoC and the necessity to correct the draft study			
M12	Submission of the feedback report to the Commission		Comments from the Commission /approval of the feedback report	
M14		Submission of draft final study including proposal for amendments if applicable		
M15			Further comments from the Commission /approval of the draft final study	
M15	Submission of the revised final study to the Commission in case the Commission had comments in M15			
M15	Final meeting in Brussels			Invoicing of the remaining 50% of the price of the contract subject to approval of the final study

### 1.2.3.1. Documents for the kick-off meeting

The kick-off meeting shall take place within 3 weeks after the signature of the contract. The objective of the meeting is to ensure the mutual understanding of the contractor's work plan and timeline for carrying out the tasks described in the terms of reference.

In this meeting, the contractor shall provide the Commission with the detailed description of the contractor's work plan and the timeline for carrying out the tasks.

### 1.2.3.2. Minutes

The contractor shall draft the minutes of the meetings with the Commission and shall submit them for comments/approval the Commission no later than 1 week after each meeting.

### 1.2.3.3. Data collected and presented per EU/EFTA country and in a comparative manner

### 1.2.3.4. Draft study

The draft study should contain:

- an explanation of methodology applied to data collection and its assessment and clearly stated data sources;
- a state of play for each of the countries concerned with regard to theoretical and practical training (point 5.6.1 of Annex V to the Directive) as well as knowledge and skills (Article 44(3) of the Directive);
- an analysis of each national health system to the extent necessary for the explanation of the relevant developments in its context;
- an assessment of convergence of the developments in the EU/EFTA countries;
- preliminary assessment on whether it would be recommended to update the minimum training requirements for pharmacists laid down in the Directive and to what extent.

### 1.2.3.5. Discussion paper for the workshop

Discussion paper based on the draft study should be of maximum 10 pages and should cover the mapping, the comparative assessment, and the conclusions/proposal, if applicable.

### 1.2.3.6. Agenda and presentations for the workshop and to the Group of Coordinators

Presentations based on the draft study should cover the mapping, the comparative assessment and the conclusions.

### 1.2.3.7. Feedback paper from workshop

The paper of maximum 5 pages shall summarise the key learning elements, including pertinent comments/positions of different stakeholders and shall include recommendations for further research/redrafting of the study if relevant.

### 1.2.3.8. Final study (and draft final study)

The final study shall be composed of all the elements of the draft study and must also include:

- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;

- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:  
“The information and views set out in this study are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission’s behalf may be held responsible for the use which may be made of the information contained therein.”
- information about the outcomes of the workshop and views of the relevant stakeholders on possible amendments to the Directive;
- conclusions on whether it would be recommended to update the minimum training requirements laid down in the Directive and to what extent. The methodology applied to this assessment should be explained;
- if the conclusion is that amendments would be appropriate, the report shall contain a proposal of amendments presented in such a way that the text could be easily used, if the Commission deems it appropriate, in the future delegated act.

The possibility to amend the Directive is subject to certain conditions laid down in Articles 21(6) and 44(2) of the Directive. These conditions should obviously be taken into account when assessing whether it would be appropriate to amend the Directive and in formulation of possible proposals for amendments.

Such updates shall not entail an amendment of existing essential legislative principles in Member States regarding the structure of professions as regards training and conditions of access by natural persons. Such updates shall respect the responsibility of the Member States for the organisation of education systems, as set out in Article 165(1) of the Treaty on the Functioning of the European Union (TFEU).

### 1.2.3.8.1. Publishable executive summary

The publishable executive summary must be provided both in English and French and must include:

- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:  
“The information and views set out in this study are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission’s behalf may be held responsible for the use which may be made of the information contained therein.”

### 1.2.3.8.2. Requirements for publication on Internet

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities,

and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on the Commission policy on accessibility for information providers, see: [http://ec.europa.eu/ipg/standards/accessibility/index\\_en.htm](http://ec.europa.eu/ipg/standards/accessibility/index_en.htm)

For the publishable versions of the study, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: <http://www.w3.org/WAI/>

### 1.2.3.8.3. Graphic requirements

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at:

[http://ec.europa.eu/dgs/communication/services/visual\\_identity/index\\_en.htm](http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm)

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.



## 2. CONTRACTUAL CONDITIONS (FOR LOT 1 AND LOT 2)

### 2.1. Nature of the contract

The title of this service contract is Mapping and Assessment of Developments for one of the sectoral professions under Directive 2005/36/EC: Lot 1 – the profession of dental practitioner; Lot 2 – the profession of pharmacist.

### 2.2. Starting date of the contract and duration of the tasks

The contract shall enter into force on the date on which it is signed by the last contracting party.

The duration of the tasks shall not exceed 15 months.

The execution of the tasks may not start before the contract has been signed. The period of execution of the tasks may be extended, only with the written agreement of the contracting parties, before the end of the period originally stated in the contract.

### 2.3. Terms of payment

Payments shall be made in accordance with Articles I.4, I.5 & II.21 of the draft service contract.

The payment scheme will consist of

- one pre-financing of 30%,
- one interim payments of 20%
- and the balance.

The schedule and the procedure for the approval of payments and the documents to be submitted are described in Articles I.5, II.21, II.22 and II.23 and in Annex I to the draft contract referred to above.

The Commission reserves the right to pay less than the amount foreseen in article I.4.1 of the contract according to tasks performed.

### 2.4. Guarantees

Guarantees are not applicable for these tendering specifications.

## 2.5. Place of performance

The place of performance of the tasks shall be the Contractor's premises or any other place indicated in the tender, with the exception of the Commission's premises.

## 2.6. Subcontracting

Subcontracting is defined as the situation where a contract has been or is to be established between the Commission and a contractor and where the contractor, in order to carry out that contract, enters into legal commitments with other legal entities for performing part of the service. However, the **Commission has no direct legal commitment with the subcontractor(s)**.

At the level of the liability towards the Commission, tasks provided for in the contract may be entrusted to subcontractors, but **the contractor retains full liability towards the Commission for performance of the contract as a whole**.

Accordingly:

- The Commission will treat all contractual matters (e.g. payments) exclusively with the contractor, whether or not the tasks are performed by a subcontractor;
- The Commission will privilege direct contacts with the contractor, who is responsible for executing the contract;
- Under no circumstances can the contractor avoid liability towards the Commission on the grounds that the subcontractor is at fault. The contractor remains notably fully responsible for timely execution.

A contract which includes subcontracting is subject to certain general conditions in particular the provisions on subcontracting, checks and audits, and confidentiality. Where justified by the subject matter of the contract, a statement of confidentiality may be required to be submitted to the Commission. **The subcontracting arrangement between the contractor and his subcontractor is supposed to render directly applicable all those contractual obligations with regard to the Commission to the subcontractor.**

Consequently, the bid must clearly identify the subcontractor(s) and document their willingness to accept the tasks and their acceptance of the terms and conditions set out in paragraph 3.2, in particular article II.24 of the standard service contract by submitting the form in annex 6.4, filled in and signed.

Tenderers must inform the subcontractor(s) and include in their sub-contracting documents that Article II.24 of the standard service contract may be applied to sub-contractors.

Once the contract has been signed, Article II.10 of the above-mentioned service contract shall govern the subcontracting.

Special attention of tenderers is brought to Article II.10.4, according to which the contracting authority may request the contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.18.1.

### 2.7. Joint Offers

A joint offer is a situation where an offer is submitted by a group of tenderers. If awarded the contract, the tenderers of the group will have an equal standing towards the Commission in executing a supply, service or works contract.

The Commission will not request consortia to have a given legal form in order to be allowed to submit a tender, but reserves the right to require a grouping to adopt a given legal form **before the contract is signed** if this change is necessary for proper performance of the contract. This can take the form of an entity with or without legal personality but offering sufficient protection of the Commission's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association).

The documents required and listed in the present specifications must be supplied by every member of the grouping; the checklist in annex 6.6 will help verifying the level of information to be provided according to the role of each entity in the tender.

Each member of the grouping assumes a joint and several liability towards the Commission.

To this end all members of the grouping should sign a **power of attorney** (see models in annex 6.5). This document must be scanned and included in the offer. For groupings not having formed a common legal entity, model 1 should be used, and for groupings with a legal entity in place model 2.

**The offer (Tender Preparation Report) has to be signed by the joint tender leader (hand or electronic signature, as explained in section 1 of the invitation to tender).**

Partners in a joint offer assume joint and several liability towards the Commission for the performance of the contract as a whole.

Statements, saying for instance: “that one of the partners of the joint offer will be responsible for part of the contract and another one for the rest”, or “that more than one contract should be signed if the joint offer is successful”, are thus incompatible with the principle of joint and several liability. The Commission will disregard any such statement contained in a joint offer, and reserves the right to reject such offers without further evaluation, on the grounds that they do not comply with the tendering specifications.

**An economic operator can only participate once as a tenderer**, whether as sole tenderer, leader in a joint tender or partner in a joint tender. **The economic operator may however agree to act as a subcontractor in a distinct bid** from which it is participating as either of the aforementioned options. However, such a situation is not advisable for the high potential of conflicts of interest it may generate.

### 3. GENERAL TERMS AND CONDITIONS FOR THE SUBMISSION OF TENDERS (FOR LOT 1 AND LOT 2)

These specifications follow the publication of a contract notice in OJ S.

#### 3.1. How to submit a tender : Registration in the Participant Register and validations by the EU Validation services

In order to submit a tender using eSubmission, tenderers (each member of the group in the case of a joint tender) will need to register in the European Commission's Participant Register - 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 in the [PIC-management Quick Guide for Economic Operators](#). Tenderers already registered in the Participant Register shall reuse their existing PICs when preparing tenders in e-Submission.

In the course of the procedure the EU Validation Services (at Research Executive Agency) may contact tenderers (each member of the group in the case of a joint tender) via the Participant Register and ask for supporting documents with respect to the legal existence and status. The notifications concerning the legal status validation will be sent to the e-mail address of the contact person indicated in the Participant Register. It is the responsibility of the tenderer (each member of the group in the case of a joint tender) to provide a valid e-mail address and to check it. Please note that a request for supporting documents in no way implies that the tenderer has been successful.

The documents that may be requested by the EU Validation Services in the course of the procedure are listed in Annex 6.7

The documents that shall be submitted with the tender in eSubmission are listed in the checklist available in Annex 6.6.

#### 3.2. Access to the market

The present procurement documents are drawn up in respect 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, 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

Participation in procurement procedures is open on equal terms to all natural and legal persons from one of the EU Member States and to all natural and legal persons 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. It is also open to international organisations.

Where the Plurilateral Agreement on Government Procurement (GPA) concluded within the WTO applies, the contracts are also open to nationals of the countries that have ratified this Agreement, on the conditions laid down therein.

The parties to the GPA can be consulted on the following web page:  
[https://www.wto.org/english/tratop\\_e/gproc\\_e/gp\\_gpa\\_e.htm](https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm).



For British tenderers:

Please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force, tenderers from the UK could be rejected from the procurement procedure.

Operators in third countries which have signed a bilateral or multilateral agreement with the European Union in the field of public procurement must be allowed to take part in the tendering procedure on the conditions laid down in this agreement. The Commission refuses tenders submitted by operators in third countries which have not signed such agreements for the present call for tender.

The Protocol on the Privileges and Immunities or, where appropriate, the Vienna Convention of 24 April 1963 on Consular Relations shall apply to this invitation to tender.

#### **Variants are not allowed.**

The Commission reserves the right to evaluate and award a contract, separately, for each lot. When several lots are proposed to be awarded to the same tenderer, the Commission may conclude one single contract for these lots.

#### **3.3. Opportunities for Small and Medium sized Enterprises**

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs has the task to promote opportunities for Small and Medium sized Enterprises (SMEs) and is aiming in its activities to facilitate the activities of SMEs. In this context, **SMEs are particularly encouraged to submit tenders** either on its own if feasible or by constituting a bid using either of the options mentioned in paragraphs 2.6 and 2.7.

The **Enterprise Europe Network** provides advice on tender opportunities and training in relation to procurement, which may be of assistance to newly initiated tenderers. Please refer to the following web-site for further details:

<http://een.ec.europa.eu/content/advice-eu-law-and-standards>

The Commission has further published a brochure on "Doing business with the European Commission – Tips for potential contractors":

[http://ec.europa.eu/budget/library/biblio/publications/business/doing\\_business\\_en.pdf](http://ec.europa.eu/budget/library/biblio/publications/business/doing_business_en.pdf)

## 4. FORM AND CONTENT OF THE TENDER (FOR LOT 1 AND LOT 2)

### 4.1. Structure of the tender

- Tenders shall be perfectly legible so there can be no doubt as to words and figures.
- Tenders shall be clear and concise.
- Tenders shall be written in one of the official languages of the European Union.
- Tenders shall include the information and documents requested by the Commission in order to assess the tender. In order to help tenderers presenting a complete tender, a checklist of the documents to be submitted is provided in annex 6.6. This checklist does not need to be included in the tender, but it is encouraged to use it in order to ease the assessment of the tenders;
- Prices shall be established in euros.

All tenders must be submitted using the eSubmission application and shall contain all the following information:

#### *4.1.1. Administrative information*

**Tenderers** may choose between presenting a **joint tender** (see 2.7) and introducing a tender as a **sole economic operator**, in both cases with the possibility of having one or several subcontractors (see section 2.6).

Whichever type of bid is chosen, the tender shall stipulate the legal status and role of each legal entity in the tender proposed and the monitoring arrangements that exist between them and, failing this, the arrangement they foresee to establish if they are awarded the contract (see 0 and 2.7).

In the e-Submission application the tenderers should fill out the required identification information in line with the instructions in the e-Submission Quick Guide available at: [https://webgate.ec.europa.eu/esubmission/assets/documents/manual/quickGuide\\_en.pdf](https://webgate.ec.europa.eu/esubmission/assets/documents/manual/quickGuide_en.pdf). The sole tenderer or all members of a joint tender must be identified with a PIC – Participant Identification Code. No PIC is needed for subcontractors.

It is not required at the level of the tender submission, to attach neither Legal Entity Form nor Financial Identification Form.

#### *4.1.2. The Exclusion and Selection Criteria Form*

Tenderers or their representatives shall provide a declaration on their honour, duly signed and dated in which they:

1. state whether or not they are in one or more of the situations referred to in Articles 136 to 140 and 141 of the Financial Regulation and detailed in the form;
2. state whether they fulfil the selection criteria

3. undertake to submit to the Commission any additional document relating to the exclusion/selection criteria, that the Commission considers necessary to perform its checks, within fifteen calendar days following the receipt of the Commission's request.

To this end, tenderers must fill in and sign the form in Annex 6.1 to these specifications.

The declaration(s) shall be signed by an authorised representative either with advanced electronic signature based on qualified certificates or by scanning and uploading a hand signed copy.

The hand-signed originals of the declaration on honour must be sent by letter to the contracting authority's postal address indicated under Heading I.1 of the contract notice at the latest on the first working day following the electronic submission of tender.

**Where the bid involves more than one legal entity (including subcontractors), each entity must provide the form.**

#### *4.1.3. Evidence relating to the selection criteria*

Tenderers shall provide proof of their economic and financial capacity by submitting the documents stated under paragraph 5.2.2 below. In case of a joint tender/tender with subcontractors, the documents concerning each economic operator shall be submitted under the respective party name.

Tenderers shall equally provide the proof *of their capacity to pursue professional activity and* of their professional and technical capacity by submitting the documents required under paragraph 5.2.3 below.

If evidence has already been provided for another procurement procedure and if the documents are up to date, reference can be made to the earlier procedure. The declaration on honour stating the reference of the procedure and the confirmation that there has been no change in the situation must be uploaded in the eSubmission application.

#### *4.1.4. Technical proposal*

The technical proposal needs to be uploaded in the step "Tender Data" of the wizard of the e-Submission application. The e-Submission application allows attachment of as many documents as necessary.

Tenderers shall include in their bids a **technical proposal addressing the aspects detailed in the technical specifications** in section 1.1.

The technical proposal shall comply with the technical specifications and provide, as a minimum, the information specifically requested.

The following aspects should in particular be taken into consideration when drafting the tender:

- (a) methodology for implementation;
- (b) reasons for the proposed methodology;
- (c) project management and procedures for internal evaluation;
- (d) level of involvement and activity of other stakeholders;
- (e) role of each partner in case of a joint bid and/or use of subcontractors, the role of each partner and subcontractor in the implementation of the contract;
- (f) team proposed for implementation of the contract. The composition of the team, which will be implementing the project must be properly described. Team staff should be singled out by function (E.g. project managers, administrator, secretary, expert, technical assistant);
- (g) a plan of action with description of activities and their timing;
- (h) measures concerning risk assessment, monitoring and quality control. Due consideration should be given to the award criteria and method as stipulated under section 5.3 in this document.

Please note that, to grant equal treatment of all tenders, **it is not possible to modify offers after their submission in relation to the technical and financial proposals.**

Please note that incomplete financial or technical proposals may have a considerable negative impact the evaluation on award criteria. Proposals deviating from the technical specifications risk to be considered as non-conform to the specifications.

Tenderers must provide a specific technical proposal for each of the lots they are offering.

**The technical specifications and the tenderer's bid shall be integral parts of the contract and will constitute annexes to the contract.**

##### *4.1.5. Financial proposal*

A complete financial proposal, including the breakdown of the price, to be provided per category, as indicated in the tender specifications needs to be uploaded in step "Tender Data" of the wizard of the e-Submission application.

The total price (including any options and renewals) needs also to be encoded directly in the e-Submission application (Total amount).

It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the relevant tab of the eSubmission application corresponds exactly to the value reflected in the uploaded financial proposal. In case of discrepancies, only the value reflected in the financial proposal will be taken into account.



**Tenderers must use the following format to formulate their financial proposal:**

<i>Price component</i>	<i>Unit price</i>	<i>Quantity</i>	<i>Total</i>
<i>Period 1(delete it if only one period, divide it by tasks or periods when necessary)</i>			
Human resources			
Person X (role)			
Person Y (role)			
.....			
Subtotal (1)			
Other			
Item X			
Item Y			
.....			
Subtotal (2)			
<b>TOTAL (1+2)</b>			

The tenderer's attention is drawn to the following points:

- (1) prices must be expressed in euros;
- (2) **prices should be quoted free of all duties, taxes and other charges, i.e. also free of VAT.** 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 (OJ 152 of 13 July 1967). 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 is to 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;

- (3) This invitation to tender relates to several lots. Tenderers shall indicate a separate price for each of the lots for which they are submitting a tender. They may indicate any price reduction they are prepared to offer in the event of being awarded more than one lot. However, this reduction will not be taken into account to determine the most cost effective tenderer for each individual lot.
- (4) Prices shall not be conditional and be directly applicable by following the technical specifications.
- (5) **Prices shall be fixed** and not subject to revision
- (6) The reference price for the award of the contract shall consist of:

**the price payable**, as stated in Article I.4.1 of the contract.

In any case, this amount constitutes the maximum amount payable for the services performed.

For each category of staff to be involved in the project, the tenderer must specify:

- the total labour costs;
- the **daily rates** and **total number of days** (man-days) each member of staff will contribute to the project;
- other categories of costs, indicating the nature of the cost, the total amount, the unit price and the quantity. Flat-rate amounts should be avoided. If, exceptionally, they are used, specimen quotations for the flat-rate amounts must be provided;
- Meetings with the Commission:

**Kick-off meeting** (estimated timing: M1)

**2 Interim meetings** (estimated timing: M4 and M11)

**Final meeting** (estimated date: M15)

All the meetings will take place at the Commission's premises, the exact dates shall be agreed in advance between the Commission and the contractor.

Estimated duration of each of the meetings: half a day.

**Bids involving more than one legal entity must specify the amounts for each legal entity.**

**The Commission will reject tenders where no technical offers or financial offers are proposed. Non-compliance with the minimum requirements in section 1.1 will also result in rejection from award.**

**The Commission reserves the right, however, to request clarification of the tender after the opening. It may furthermore require (additional) evidence in relation to the administrative information, exclusion and selection criteria. The information required shall be provided within a time-limit stipulated in its request and under the conditions explained in section 3.3.**

**5. ASSESSMENT AND AWARD OF CONTRACT (FOR LOT 1 AND LOT 2)**

The assessment will be based on the information provided in the tender. The Commission reserves the right to use any other information from public or specialist sources. This assessment will be performed by applying the criteria set out in these specifications. To award the contract, the assessment of admissible bids (see paragraph 1 of the Invitation to tender) will be carried out under exclusion, selection and award criteria in no particular order.

The aim of this assessment is:

- (1) to verify compliance with the exclusion criteria as defined in article 106 and 107 of the Financial Regulation, in order to determine whether the tenderer can take part in the procedure and, where applicable, be awarded the contract;
- (2) to verify compliance with the selection criteria, technical and professional capacity and economic and financial capacity required by these specifications;
- (3) to verify compliance with the minimum requirements specified in the tender documents and to assess the technical and financial offer in relation to the award criteria.

**5.1. APPLICATION OF EXCLUSION CRITERIA AND EXCLUSION OF TENDERERS: IDENTICAL FOR LOT 1 AND LOT 2, AND FOR THE CASE IN WHICH THE TENDERER SUBMITS A PROPOSAL FOR BOTH LOTS.**

*5.1.1. Declaration*

As mentioned above under paragraph 4.1.2 tenderers or their representatives shall provide the form in Annex 6.1 duly signed and dated in which they declare:

1. not to be in one or more of the situations referred to in Articles 136 to 140 and 141 of the Financial Regulation and detailed in the form;
2. to undertake to submit to the Commission any additional document relating to the exclusion criteria, that the Commission considers necessary to perform its checks, within 15 days following the receipt of the Commission's request.

*5.1.2. Grounds for disqualification*

In accordance with Article 141 of the Financial Regulation, a contract for a given procedure may not be awarded to an economic operator who:

- is in an exclusion situation established in accordance with Article 136 to 140;
- has misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;
- was previously involved in the preparation of procurement documents where this entails a distortion of competition that cannot be remedied otherwise.

**5.1.3. Evidence**

The tenderer to whom the contract is to be awarded shall provide, within the 15 days following the receipt of the letter informing him of the proposed award of the contract and preceding the signature of the contract, the evidence confirming the declaration referred to in paragraph 5.1.1,(for the details of requested documents please see directly the text of the declaration).

The Commission 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 his honour that the documentary evidence has already been provided to the Commission in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Commission services to check this evidence.

You may refer to the e-Certis web-site listing the certificates available in EU Member States:

<http://ec.europa.eu/markt/ecertis/login.do>

**5.2. APPLICATION OF SELECTION CRITERIA (SELECTION OF TENDERERS): IDENTICAL FOR LOT 1 AND LOT 2, AND FOR THE CASE IN WHICH THE TENDERER SUBMITS A PROPOSAL FOR BOTH LOTS.**

This part of the tender concerns the criteria and evidence relating to the technical and professional capacity and economic and financial capacity of the service provider(s) involved in the bid. It should also contain any other document that the tenderer(s) wish(es) to include by way of clarification.

**An economic operator may rely on the capacities of other entities**, regardless of the legal nature of the links which it has with them. In that case, evidence must be provided that it will have at its disposal the resources necessary for performance of the contract, for example by producing a clear undertaking on the part of those entities to place those resources at its disposal.

If the economic and financial selection criteria are fulfilled by relying on a third party, the contracting authority may demand, if that tender wins the contract, that this third party signs the contract (becomes a contractor) or, alternatively, provides a joint and several first-call guarantee.

If the third party chooses to sign the contract, the contracting authority should ensure that it is not in exclusion situation and it has access to the market.

**If several service providers are involved in the bid**, each of them must have the professional and technical capacity to perform the tasks assigned to them in the tender and have the necessary economic and financial capacity.

This rule applies to all legal entities once they have chosen to be tenderers. If the tender includes subcontractors, the Commission reserves the right to request evidence of their economic and financial capacity, where the tasks subcontracted represent a substantial part of the contract.

5.2.1. Selection criteria

<b><u>SELECTION CRITERIA</u></b>
<b>1. FINANCIAL AND ECONOMIC CAPACITY</b>
<p>1.1 Turnover of the last two financial years above EUR 150 000; this criterion applies to the tenderer as a whole, i.e. the combined capacity of all members of a group in case of a joint tender.</p> <p>1.2 Sufficient financial capacity in relation to the pre-financing foreseen under the contract</p> <p>1.3 Reliability of the mitigating measures presented to cover possible deficiencies in the evidence presented for the above criteria.</p>
<b>2. TECHNICAL AND PROFESSIONAL CAPACITY</b>
<p>2.1 Tenderers must prove their capacity to collect and analyse data from all the EU Member States and EFTA States, including analysis of national legislation, proven by at least 1 project delivered (or taking part in a consortium delivering such project) in the last three years showing a similar geographical coverage.</p> <p>2.2 Tenderers must demonstrate expertise in the field of drafting similar type of studies by at least 1 similar project delivered in the last three years in English (or taking part in a consortium delivering such project).</p> <p>2.3 Tenderers must demonstrate capacity to put together a team consisting of: (1) Team Leader with university level education and at least 10 years of professional experience in the area of managing European projects and international teams over the last 15 years; (2) at least one expert qualified as dental practitioner with at least 5 years of experience in dental education over the last 10 years; (3) at least one lawyer specialized in Internal Market law with at least 5 years' experience in the field over the last 10 years; (4) experts responsible for each country (EU and EFTA countries) specialized in /knowledgeable of dental education and having a proven adequate working knowledge of the official language(s) of the respective country. There can be one expert per several countries.</p> <p>All the team members should have a proven adequate working knowledge of English.</p> <p>2.4 Tenderers must demonstrate experience in organisation of events/workshops by at least 1 similar project delivered in the last three years that also required the organisation of a similar event/workshop (or taking part in a consortium delivering such project).</p>

These criteria will be assessed on the basis of the documents referred to in 5.2.2 and 5.2.3.

**5.2.2. Evidence of the economic and financial capacity of the service provider(s)**

All tenderers shall provide proof of their economic and financial capacity by submitting the following documents:

- a) A full copy of the concerned legal entities' annual accounts (balance sheet, profit and loss account, notes on the accounts and auditors' remarks when applicable) of the last two years, as approved by the general assembly of the company and, where applicable, audited and/or published. These documents must be signed by the authorised representative of the tenderer;
- b) Alternatively to a), a filled out Annex 6.3. This document must be signed by an authorised representative of the tenderer.
- c) a statement of overall turnover and turnover concerning the tasks, supplies or services covered by this contract for the last three financial years;
- d) Appropriate statements from banks or evidence of professional risk indemnity insurance, for legal entities facing the impossibility to fully present evidence a).

If, for some exceptional reason which the Commission considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Commission considers appropriate. In any case, the Commission must at least be notified of the exceptional reason and its justification in the tender. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

The Commission may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraph 1 if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that it complies with the requirements of the present call for tenders. In such a case, the tenderer shall indicate in the tender reference to the contract and Commission service for which the evidence has been provided, in order to allow the Commission services to check this evidence.

**5.2.3. Evidence of the technical and professional capacity of the service provider(s)**

The ability of service providers to perform services will be assessed in particular with regard to their know-how, efficiency, experience and reliability as specified in paragraph 5.2.1.

Evidence of the technical and professional capacity of the providers involved in the tender may be furnished on the basis of the following documents:

- a) the educational and professional qualifications of the service provider or contractor and/or those of the firm's managerial staff and, in particular, those of the person or persons responsible for providing the services or carrying out the tasks; The Europass curriculum vitae format (<http://europass.cedefop.europa.eu/en/documents/curriculum-vitae>) shall be filled in and signed, by each person involved in the execution of the tasks foreseen in the tender. The precise contractual link with the tenderer will also be described.

This evidence refers to selection criterion 2.3.

b) a list of the services carried out in the last three years, with the sums, dates and place. The list of the most important services shall be accompanied by certificates of satisfactory execution;

This evidence refers to selection criteria 2.1, 2.2 and 2.4.

By submitting a tender, each legal entity involved therein accepts the possibility of a check being carried out by the Commission on its technical capacities and, if necessary, on its research facilities and quality control measures.

In addition, all tenderers are informed that they may be asked to prove that they are authorised to perform the contract under national law, as evidenced by inclusion in a professional or trade register, by a sworn declaration or certificate, by membership of a specific organisation, by express authorisation, or by entry in the VAT register.

#### *5.2.4. Evidence of the legal and regulatory capacity*

Not applicable to this contract.

### **5.3. APPLICATION OF AWARD CRITERIA (ASSESSMENT OF TENDERS): IDENTICAL FOR LOT 1 AND LOT 2, AND FOR THE CASE IN WHICH THE TENDERER SUBMITS A PROPOSAL FOR BOTH LOTS.**

The contract will be awarded to the most cost-effective tender for each lot. The following award criteria will be applied to tenders under each lot:

1. Quality and relevance of the proposed methodology to collect, analyse and present data (60 points): The main award criterion will be the soundness of the proposed methodology. This criterion will evaluate the overall methodological framework proposed for completing the tasks listed in sections 1.1. and 1.2.

2. Quality of the proposed work plan, project management structure and resource allocation within the team (20 points): This criterion will assess how the roles and responsibilities of the proposed team and of the economic operators (in case of joint tenders, including subcontractors if applicable) are distributed for each task. It will also assess the global allocation of time and resources to the project and to each task or deliverable, and whether this allocation is adequate for the work. The tender should provide details on the allocation of time and resources and the rationale behind the choice of this allocation. The tender should include a summary table indicating the members of the team and describing their roles and involvement in each project phase. It should also include the number of hours / days each team member will spend on each project phase.

3. Quality of the measures concerning risk assessment, monitoring and quality control (20 points): This criterion will assess risk assessment, monitoring and the quality control system applied to the service foreseen in the tender specifications concerning the quality of the deliverables, the verification of the compliance with the rules on citation and intellectual property rights, the language quality check, and continuity of the service in case of absence of the member of the team. The risk assessment, monitoring and quality system should be detailed in the tender and specific to the tasks at hand; e.g. a generic quality system will result in a low score. More specifically, a risk assessment should be provided for potential non-availability of

## 5. Assessment and award of contract

data, e.g. for cases where contact institutions on national level do not provide the requested information.

No	Qualitative award criteria	Weighting (maximum points)
1.	<i>Quality and relevance of the proposed methodology to collect, analyse and present data</i>	60
2.	<i>Quality of the proposed work plan, project management structure and resource allocation within the team</i>	20
3.	<i>Quality of the measures concerning risk assessment, monitoring and quality control</i>	20
<b>Total number of points</b>		100

Each lot will have a separate evaluation procedure. The selected tender is assessed according to the above qualitative award criteria and the weighting applicable to each criterion.

### ***Tenders scoring***

*\* less than 70 % in the overall points total or*

*\* less than 50% in the points awarded for a single criterion*

*will be excluded from the rest of the assessment procedure.*

### **Price Award criterion**

**Total price**

Tenders presenting a total price superior to the maximum amount of € 190.000 for Lot 1 and € 190.000 for Lot 2 will be excluded from the rest of the assessment procedure.

The contract will be awarded to the tender which is the most economically advantageous on the basis of the ratio between the total points scored and the price.



Final Evaluation										
score for tender X	=	$\frac{\text{cheapest price}}{\text{price of tender X}}$	*	100	*	price weighting (30 %)	+	total quality score (out of 100) for all award criteria of tender X	*	quality criteria weighting (70%)
<p><i>Where the "cheapest price" refers to the lowest price of the tenders that have reached the minimum quality level set above.</i></p>										

**Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, may result in a significantly lower score. Where essential elements of these specifications are not expressively covered by the tender, the Commission may decide to give a zero mark for the relevant qualitative award criteria.**

**The tender may be rejected as non-compliant, when the minimum requirements set in the specifications are not met.**

#### 5.4. Information for tenderers

The Commission will notify all tenderers of decisions reached concerning the outcome of the procedure, indicating the grounds on which the decision was taken. This also applies to a decision not to award a contract or to cancel the procedure.

The Commission will inform the rejected tenderers of the reasons for their rejection. Each tenderer who is not in an exclusion situation and whose tender is compliant with the procurement documents and who makes a request in writing, shall be informed of the characteristics and relative advantages of the selected tender, of the name of the successful tenderer and of the price or contract value.

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

#### 5.5. Award of the contract

The procurement procedure is concluded by a contract signed by the parties. In this case, the General Terms and Conditions applicable to service contracts referred to above shall apply.

## **5. Assessment and award of contract**

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the tenderer's agreement in writing.

The Commission shall not sign the contract or framework contract with the successful tenderer until a standstill period of 10 calendar days has elapsed, counting from the day after simultaneous dispatch of the notification by electronic means to all tenderers (successful and unsuccessful).

After the award, during standstill period, the Commission will request to the tenderer proposed for award the evidence on exclusion criteria defined in section 5.1.3. If this evidence was not provided or proved to be unsatisfactory the Commission reserves the right to cancel the award procedure or to change the award decision to the benefit of the next best ranked tenderer on condition that he satisfies with the provision of the evidence on exclusion.

6. ANNEXES

**ANNEXES**

**6.1. EXCLUSION AND SELECTION CRITERIA FORM (INVITATION TO TENDER NO 751/PP/GRO/IMA/18/1131/10885)**

**Declaration on honour on  
exclusion criteria and selection criteria**

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

<i>(only for natural persons)</i> himself or herself	<i>(only for legal persons)</i> 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’)

**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 national legislation or regulations;	<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 law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;	<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 selection criteria or in the performance of a contract;	<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 the following:		
(i) fraud, within the meaning of 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 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
(v) terrorist-related 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;	<input type="checkbox"/>	<input type="checkbox"/>
(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
e) the person has shown significant deficiencies in complying with the main obligations in the performance of a contract 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 an Authorising Officer, 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) for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to: i.facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, 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 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.decisions of the ECB, the EIB, the European Investment Fund or	<input type="checkbox"/>	<input type="checkbox"/>

international organisations; iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.		
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## II – Situations of exclusion concerning natural persons with power of representation, decision-making or control over the legal person

*Not applicable to natural persons, Member States and local authorities*

(2) declares that a natural 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 company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations:	YES	NO	N/A
Situation (c) above (grave professional misconduct)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (d) above (fraud, corruption or other criminal offence)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (e) above (significant deficiencies in performance of a contract )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (f) above (irregularity)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 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)	<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

(4) declares that the above-mentioned person:	YES	NO
h) has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure.	<input type="checkbox"/>	<input type="checkbox"/>

## 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. 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 the persons that are members of the administrative, management or supervisory body. It must also provide the following evidence concerning the person itself and concerning the natural or legal persons which assume unlimited liability for the debt of the person:

For situations described in (a), (c), (d) or (f), 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 (a) or (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 procurement procedure. 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
<i>Insert as many lines as necessary.</i>	

## VII – Selection criteria

(5) 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 5.2.4 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>	X
(b) It fulfills the applicable economic and financial criteria indicated in section 5.2.1 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Turnover of the last two financial years above EUR 150 000; this criterion applies to the tenderer as a whole, i.e. the combined capacity of all members of a group in case of a joint tender.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sufficient financial capacity in relation to the pre-financing foreseen under the contract.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reliability of the mitigating measures presented to cover possible deficiencies in the evidence presented for the above criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) It fulfills the applicable technical and professional criteria indicated in section 5.2.1 of the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tenderers must prove their capacity to collect and analyse data from all the EU Member States and EFTA States, including analysis of national legislation, proven by at least 1 project delivered (or taking part in a consortium delivering such project) in the last three years showing a similar geographical coverage.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tenderers must demonstrate expertise in the field of drafting similar type of studies by at least 1 similar project delivered in the last three years in English (or taking part in a consortium delivering such project).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tenderers must demonstrate capacity to put together a team consisting of: (1) Team Leader with university level education and at least 10 years of professional experience in the area of managing European projects and international teams over the last 15 years; (2) at least one expert qualified as dental practitioner with at least 5 years of experience in dental education over the last 10 years; (3) at least one lawyer specialized in Internal Market law with at least 5 years' experience in the field over the last 10 years; (4) experts responsible for each country (EU and EFTA countries) specialized in /knowledgeable of nursing education and having a proven adequate working knowledge of the official language(s) of the respective country. There can be one expert per several countries.  All the team members should have a proven adequate working knowledge of English.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tenderers must demonstrate experience in organisation of events/workshops by at least 1 similar project delivered in the last three years that also required the organisation of a similar event/workshop (or taking part in a consortium delivering such project).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(6) if the above-mentioned person is the <b>sole tenderer</b> or the <b>leader in case of joint tender</b> , 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 the selection criteria for which a consolidated assessment will be made as provided in the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## VII – 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. 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:

<b>Document</b>	<b>Full reference to previous procedure</b>
<i>Insert as many lines as necessary.</i>	

***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



## 6.2. Model Guarantee

### [MODEL] LETTER FOR PRE-FINANCING FIRST DEMAND GUARANTEE<sup>10</sup>

[Financial institution/Bank (Letterhead)]  
[Place/Date]

European Community  
Represented by the European Commission  
Directorate-General for Internal Market, Industry,  
Entrepreneurship and SMEs – [Unit]  
B – 1049 Belgium

**Reference: Contract [Insert number and exact title]**

#### ARTICLE 1 – DECLARATION ON GUARANTEE, AMOUNT AND PURPOSE

We, the undersigned [*insert name and address of the financial institution or bank*] ('the Guarantor') hereby confirm that we give the European Union, represented by the European Commission ('the Commission'), an unconditional, irrevocable and independent first-demand guarantee consisting in the undertaking to pay to the Commission a sum equivalent to the amount of:

EUR [*insert amount in figures and in words*]

upon simple demand, for guarantee of the pre-financing(s) stipulated in the contract [*insert number and exact title*], [*Option 1:* ('the grant agreement') signed between the Commission and [*insert name and address*]<sup>11</sup>, ('the Beneficiary')] [*Option 2:* ('the grant decision') taken by the Commission and addressed to the [*insert name and address*], ('the Beneficiary')] [*Option 3:* ('the contract') concluded between the Commission and [*insert name and address*], ('the Contractor')].

#### ARTICLE 2 – EXECUTION OF GUARANTEE

If the Accounting Officer of the Commission gives notice that the Contractor has for any reason failed to reimburse pre-financings paid by the Commission, we, acting for account of the Contractor, shall pay immediately up to the above amount, in EUR, without exception or objection, into [ a bank account designated by the Commission] [the following bank account: [*insert number*]], on receipt of the first written request from the Commission. We shall inform the Commission in writing as soon as the payment has been made.

#### ARTICLE 3 – OBLIGATIONS OF THE GUARANTOR

1. We waive the right to require exhaustion of remedies against the Contractor, any right to withhold performance, any right of retention, any right of avoidance, any right to offset, and the right to assert any other claims which the Contractor may have against the Commission under the contract or in connection with it or on any other grounds.
2. Our obligations under this guarantee shall not be affected by any arrangements or agreements made by the Commission with the Contractor which may concern its obligations under the contract.

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<sup>10</sup> The footnotes are internal instructions for the authorising officers only and must be deleted before the guarantee is signed. [Plain text]: items to be filled in. [*Text in italics*]: these items are optional and may be deleted depending on the context of the guarantee.

<sup>11</sup> In case of multi-beneficiaries arrangements please refer to the name and address of the coordinator if the coordinator is solely responsible for repayment to the Commission at the time of payment of the balance (see e.g. article II.26.1 of the model grant agreement with multiple beneficiaries).

3. We shall inform immediately the Commission in writing, by registered letter or by courier with written receipt or equivalent, in the event of a change of our legal status, ownership or address.

#### ARTICLE 4 – DATE OF ENTRY INTO FORCE

This guarantee shall come into force upon its signature. If, on the date of its signature, the [first] pre-financing has not been paid to the Contractor, this guarantee shall enter into force on the date on which the Contractor receives the [first] pre-financing.

#### ARTICLE 5 – END DATE AND CONDITIONS OF RELEASE

1. We may be released from this guarantee only with the Commission’s written consent.
2. This guarantee shall expire on return of this original document by the Commission to our offices.
3. [Option 1: This must occur at the latest 30 days after the payment of the balance under the contract or four months after the notification of the corresponding debit note.]

[Option 2: This must occur at the latest 30 days after the pre-financing under contract has been cleared through interim payment[s].]

[Option 3 to be used only if the law applicable to the guarantee imposes a precise expiry date: This must occur, in any case, at the latest, on *[indicate a precise date]*.]

4. After expiry, this guarantee shall become automatically null and no claim relating thereto shall be receivable for any reason whatsoever.

#### ARTICLE 6 – APPLICABLE LAW AND COMPETENT JURISDICTION

[Option 1: Any dispute concerning this guarantee shall be governed by and construed in accordance with the law of *[insert law applicable to the contract]* and shall fall within the sole competence of the Courts of *[insert the corresponding national courts as indicated in the contract]*.]

[Option 2: Any dispute concerning this guarantee shall be governed by and construed in accordance with the law of *[insert country of establishment of the Contractor or Bank]* and shall fall within the sole competence of the *[insert the corresponding national]* Courts.

#### ARTICLE 7 - ASSIGNMENT

The rights arising from this guarantee may not be assigned.

Done at *[insert place]*, on *[insert date]*

*[Signature]*

*[Signature]*

*[Function at the Financial Institution/Bank]*

*[Function at the Financial Institution/Bank]*

**6.3. FINANCIAL AND ECONOMIC CAPACITY OVERVIEW FORM (INVITATION TO TENDER NO 751/PP/GRO/IMA/18/1131/10885)**

<b>Financial and Economic Capacity Overview</b>			
<b>Currency : EURO</b>		<b>Figures (000)</b>	
	<b>N*</b> (* most recent figures available)	<b>N-1</b>	<b>N-2</b>
<b>Total Balance Sheet</b>			
TRADE DEBTORS <i>Amounts due by commercial customers</i>			
CAPITAL and RESERVES (Equity) <i>Amounts owned by the company</i>			
TRADE CREDITORS <i>Amounts due to commercial suppliers</i>			
SHORT TERM DEBT			
LONG TERM DEBT			
LIQUIDITY <i>Bank accounts, cash at hand</i>			
<b><u>About PROFIT &amp; LOSS</u></b>			
TURNOVER			
ORDINARY RESULT			
EXTRAORDINARY RESULT			
INCOME TAX			
NET RESULT			

**You may add any data that you would consider of vital relevance for your organisation and for the understanding of the above figures.**

Comments: Please explain BRIEFLY important variations from one year to another if appropriate. In case of negative equity or repeated losses, please explain how the future of the organisation will be ensured.

**6.4. SUBCONTRACTOR / LETTER OF INTENT 751/PP/GRO/IMA/18/1131/10885**

MAPPING AND ASSESSMENT OF DEVELOPMENTS FOR SECTORAL PROFESSIONS  
UNDER DIRECTIVE 2005/36/EC:

**(COMPLETE WITH RELEVANT LOT NUMBER)**

LOT 1: THE PROFESSION OF DENTAL PRACTITIONER

LOT 2: THE PROFESSION OF PHARMACIST

The undersigned: .....

Name of the company/organisation: .....

Address: .....

Declares hereby the intention to collaborate in the execution of the tasks subject to the above call for tender, in accordance with the terms of the offer to which the present form is annexed, if the contract is awarded to ... .... *(name of the tenderer)*.

Declares hereby accepting the general conditions attached to the tendering specifications for this call for tender, and in particular art. II.24 in relation with checks and audits.

**Full name**

**Date**

**Signature**

.....

## 6.5. POWER OF ATTORNEY

### POWER OF ATTORNEY – MODEL 1

# Agreement / Power of Attorney

## (DESIGNATING ONE OF THE COMPANIES OF THE GROUP AS LEADER AND GIVING A MANDATE TO IT)

We the undersigned:

- Signatory 1 (Name, Function, Company, Registered address, VAT Number)
- Signatory 2 (Name, Function, Company, Registered address, VAT Number)
- .....
- Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

In case the European Commission awards **[Framework]** Contract .... (« **the Contract** ») to Company 1, Company 2, ..., Company N (« **the Group Members** »), based on the joint offer submitted by them on ... .. for the supply of ..... and/or the provision of services for ... (« **the Supplies and/or the Services** »).

(1) As co-signatories of the Contract, all the Group Members:

- (a) Shall be jointly and severally liable towards the European Commission for the performance of the Contract.
- (b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(2) To this effect, the Group Members designate Company X as **Group Leader**. *[N.B.: The Group Leader has to be one of the Group Members]*

(3) Payments by the European Commission related to the Supplies or the Services shall be made through the Group Leader's bank account *[Provide details on bank, address, account number, etc.]*.

(4) The Group Members grant to the Group Leader all the necessary powers to act on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks:

- (a) The Group Leader shall sign any contractual documents—including the **[Framework]** Contract, **[Specific Agreements]** and Amendments thereto—and issue any invoices related to the Supplies or the Services on behalf of the Group Members.
- (b) The Group Leader shall act as single point of contact for the European Commission in connection with the Supplies and/or the Services to be provided under the Contract. It shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the European Commission, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the European Commission's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the European Commission in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Commission's consent.

Signed in ..... on .....

Name

Function

Company

Name

Function

Company

Name

Function

Company

Name

Function

Company



## POWER OF ATTORNEY – MODEL 2

# Agreement / Power of Attorney

### (CREATING THE GROUP AS SEPARATE ENTITY, APPOINTING A GROUP MANAGER AND GIVING A MANDATE TO HIM/HER)

We the undersigned:

- Signatory 1 (Name, Function, Company, Registered address, VAT Number)
- Signatory 2 (Name, Function, Company, Registered address, VAT Number)
- .....
- Signatory N (Name, Function, Company, Registered address, VAT Number),

Each of them having the legal capacity required to act on behalf of his/her company, HEREBY AGREE AS FOLLOWS:

In case the European Commission awards [Framework] Contract .... (« **the Contract** ») to Company 1, Company 2, ..., Company N (« **the Group Members** »), based on the joint offer submitted by them on ... .. for the supply of ..... and/or the provision of services for ... (« **the Supplies and/or the Services** »).

(1) As co-signatories of the Contract, all the Group Members:

- (a) Shall be jointly and severally liable towards the European Commission for the performance of the Contract.
- (b) Shall comply with the terms and conditions of the Contract and ensure the proper execution of their respective share of the Supplies and/or the Services.

(2) To this effect, the Group Members have set up under the laws of ..... the Group ..... (« **the Group** »). The Group has the legal form of a ..... [*Provide details on registration of the Group: VAT Number, Trade Register, etc.*].

(3) Payments by the European Commission related to the Supplies or the Services shall be made through the Group's bank account . [*Provide details on bank, address, account number, etc.*].

(4) The Group Members appoint Mr/Ms ..... as **Group Manager**.

(5) The Group Members grant to the Group Manager all the necessary powers to act alone on their behalf in connection with the Supplies and/or the Services. This mandate involves in particular the following tasks :

- (a) The Group Manager shall sign any contractual documents—including the [Framework] Contract, [Specific Agreements] and Amendments thereto—and issue any invoices related to the Supplies or the Services on behalf of the Group Members.
- (b) The Group Manager shall act as single point of contact for the European Commission in connection with the Supplies and/or the Services to be provided under the Contract. He/she shall co-ordinate the provision of the Supplies and/or the Services by the Group Members to the European Commission, and shall see to a proper administration of the Contract.

Any modification to the present agreement / power of attorney shall be subject to the European Commission's express approval.

This agreement / power of attorney shall expire when all the contractual obligations of the Group Members towards the European Commission in connection with the Supplies and/or the Services to be provided under the Contract have ceased to exist. The parties cannot terminate it before that date without the Commission's consent.

Signed in ..... on .....

Name

Function

Company

Name

Function

Company

Name

Function

Company

Name

Function

Company

## 6.6. CHECKLIST OF DOCUMENTS TO BE SUBMITTED IN THE E-SUBMISSION APPLICATION

The purpose of the table below is to facilitate the preparation of the tender by providing an overview of the documents that must be included (marked by ■) depending on the role of each economic operator in the tender (joint tender leader in joint bid, partner in joint bid, sole tenderer, subcontractor).

Some of the documents are only relevant in cases of joint bids or when subcontractors are involved. Additional documents might be necessary depending on the specific characteristics of each tender.

Description	Joint tender leader in joint bid	Partners in joint bid	Sole tenderer	Sub-contractor(s)
Power of attorney of partners in joint bid indicating the group leader ( <a href="#">see annex 6.5</a> )		■		
Evidence that the person signing the documents is an authorised representative of the tenderer	■	■	■	■
Letter of intent of subcontractor ( <a href="#">see annex 6.4</a> )				■
Exclusion and selection Criteria form ( <a href="#">see section 5.1.1</a> and <a href="#">annex 6.1</a> )	■	■	■	■
Evidence of Economic and financial capacity ( <a href="#">see section 5.2.2</a> and <a href="#">annex 6.3</a> )	■	■	■	
Evidence of Technical and professional capacity ( <a href="#">see section 5.2.3</a> ) Go to the following page to fill in the CV: <a href="http://europass.cedefop.europa.eu/en/documents/curriculum-vitae">http://europass.cedefop.europa.eu/en/documents/curriculum-vitae</a>	■	■	■	■

The following sections must be provided in the bid **for each Lot**, their absence would mean rejection of the bid for incompleteness:

Description	Joint tender leader or sole tenderer
-------------	--------------------------------------

Technical Offer (see section <a href="#">4.1.4</a> and <a href="#">1.</a> )	■
Financial Offer (see section <a href="#">4.1.5</a> )	■

Once all information and documents have been encoded and uploaded in the e-Submission application and you consider that the tender is complete, the application will require you to download the Tender Report generated by the e-Submission application. It will have to be signed (hand signature or electronic signature) and uploaded, as explained in the [eSubmission Quick Guide for economic operators](#).

Description	Joint tender leader in joint bid	Partners in joint bid	Sole tenderer	Sub-contractor	Where to upload a document in e-Submission
Tender Report	■		■		In Step "Tender Report" of the e-Submission wizard

## 6.7. DOCUMENTS WHICH MAY BE REQUESTED BY THE EU VALIDATION SERVICES IN THE COURSE OF THE PROCEDURE

- Signed **legal entity identification form**<sup>12</sup> :

- Natural Person

- Private Law Body

- Public Law Body

- **Official VAT document** or — if the entity is not registered for VAT — the proof of VAT exemption, not older than 6 months.
- Signed **Financial Identification Form, and**
- the following additional documents, where relevant:

Private body	Registration extract (not older than 6 months).
Public body	Copy of the act, law, decree or decision that established the organisation as a public body (or, if this doesn't exist, any other official legal document that proves this).
Non-profit organisation	Copy of an official document attesting that the organisation has a legal or statutory obligation not to distribute profits to shareholders or individual members.  The certificate of tax exemption may only constitute an indication of the non-profit status of the entity which has to be assessed together with other elements.
Research organisation	Copy of an official document attesting that one of the main objectives of the entity is carrying out research or technological development.
Secondary or higher education establishment	Copy of an official document attesting that the organisation is recognised such as 'secondary or higher education establishment' by the national education system and is entitled to deliver diplomas recognized by the State.
	Copy of the relevant international treaty creating the organisation under international

<sup>12</sup> Available at [http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/legal\\_entities/legal\\_entities\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm)

<p>International organisation</p> <p>International organisation of European interest</p>	<p>public law.</p>
<p>Natural person</p>	<p>Copy (legible) of valid identity card or passport</p>
<p>Entities without legal personality</p>	<p>- Copy of an official document attesting that the representatives of the entity have the capacity to undertake legal obligations on its behalf.</p> <p>- Copy of an official document attesting that the entity has the same operational and financial capacity as that of a legal entity: i.e.</p> <ul style="list-style-type: none"> <li>• a document showing patrimony/asset/capital that is separated and different from those of the members/owners of the entity, and</li> <li>• a copy of the rules providing that creditors can rely on this patrimony/asset/capital and — in case of liquidation/insolvency — are reimbursed before the patrimony/asset/capital is divided between the owners/members.</li> </ul>