INVITATION TO TENDER FOR THE PROVISION OF:

Accelerated Access Review (AAR) – a review of adaptive pathways (workstream 2)

Deadline: **20/08/2015 – 14:00:00**

ITT Reference: **59941**

**PART B –** Tender Schedules

(To be returned by Tenderers)

1. Specification
2. Executive Summary

On 20 November 2014, the Minister for Life Sciences announced the [Accelerated Access Review](https://engage.dh.gov.uk/acceleratedaccess/) (AAR). The Review will help to ensure that NHS patients benefit from earlier access to innovative medicines, diagnostics and devices, and help Government lead the global race for life sciences investment by making the UK the best place for 21st century medical innovation and product development. There are direct links to the DH Departmental priority to raise standards in health and care through the use of technology and the Review will support NHS England’s [Five Year Forward View](http://www.england.nhs.uk/ourwork/futurenhs/) commitment to accelerating the quicker adoption of cost-effective medicines, diagnostics and devices.

**Background on the AAR**

The AAR is being managed by the Office for Life Sciences (OLS), which works across the Department of Health and the Department for Business, Innovation and Skills, to champion research, innovation and the use of technology to transform health and care services. The Review is chaired by Sir Hugh Taylor, supported by Sir John Bell (chair of the Review Advisory Group).

The AAR aims to revolutionise the speed at which 21st century innovations in medicines and medical technologies get to NHS patients and their families. Currently it can take 10-15 years to get a new product from discovery into the system. The process can cost over £1 billion and uptake of innovative products by the NHS is perceived to be slow. By capitalising on advances in genomics, data, digital health and informatics, the review will address these challenges and accelerate access to cost effective new products. By making the UK a world leading place to design, develop and deploy medical innovations, the review will stimulate investment and create a stronger NHS.

The AAR has a broad scope and will look at medicines, devices, diagnostics and digital health products, focussing on end-to-end pathways drawing together four workstreams:

1. *Articulating need, priorities and principles for innovation*: developing a transparent framework for early dialogue and collaboration with the NHS to drive transformative, needs-led innovation and support partnerships;
2. *Accelerated development pathways*: streamlining regulatory processes and ensuring that existing accelerated pathways are clearly articulated;
3. *Affordable national funding models to drive innovation*: includes flexible reimbursement models, NICE’s scope and the CDF; and,
4. *Supporting affordable adoption and diffusion*: accelerating the speed at which clinically and cost-effective innovative products are commissioned and get to NHS patients.
5. The Requirement

The AAR team are looking for an organisation that will work closely with the team to help rapidly identify and co-design possible solutions to the challenges of workstream 2, in particular building a new accelerated pathway. This work will be delivered in parallel with a review of the [Early Access to Medicines Scheme](https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams) (EAMS) – (ITT ref number 59959). The contractor will be expected to work closely with this second piece of work, and take account of its conclusions. It is possible that one contractor may deliver both pieces of work, in which case we would expect to see significant efficiencies from such a delivery arrangement. The contractor should also draw on the two pieces of work conducted in the first phase of the Review, by Deloitte and RAND (available on the [AAR website](https://www.gov.uk/government/organisations/accelerated-access-review)), to avoid any duplication.

A short, status-summary report will be required in mid-September as input to the Review’s own interim report. The final products for this piece of work will be a concise report setting out key messages and thinking, summarising the deliverables outlined below. This should be accompanied by a PowerPoint summary and supporting documentation.

The deliverables will be evidence of the benefits and risk of options to streamline the overall process for development and regulation of new healthcare technologies, from the point at which they are ready for clinical trial, to their initial approval by the regulator and reimbursement agency(ies). The full range of options evaluated should be presented, with clear, evidence-based recommendations of priorities for action. The evidence presented must include an analysis of the impact, and where possible operational cost, of different options. Annexes of data and supporting evidence must also be supplied. Emerging findings should be based on discussions with stakeholders from across the sector, rather than being purely theoretical.

**Aims of Workstream 2:**

1. To identify:

* where and how the current processes and pathways through which innovative medicines, devices and diagnostics are developed, from proof of concept through regulation, might be streamlined;
* the strengths and weaknesses of the current pathways and processes;
* particular areas within current pathways and processes that will be challenged by the new types of product and changes in the healthcare environment, assessing the degree to which the system is future-proofed and identifying priority areas for change. Changes may include packages of incentives, guidance, regulatory changes and clinical support.

1. To provide evidence of the feasibility of options and their potential impacts if deployed in a new accelerated pathway.

**Key areas of enquiry and questions to be addressed:**

1. **European Adaptive Pathways**.
   1. What are the implications (including advantages/ disadvantages/ opportunities/ threats, timings, risks and costs) for the UK of the current European Medicines Agency (EMA) concept and pilot programme for adaptive pathways?
   2. How might these be exploited by the UK to develop a new accelerated pathway?
   3. This work should be informed by dialogue with the recently launched Innovative Medicines Initiative (IMI)/EMA project on adaptive pathways.
2. **Clinical trials**.
   1. Summarise the available data on the UK’s current comparative/competitive position as a destination for global clinical trials
   2. Gather data to demonstrate the potential for further streamlining of the UK clinical trials process, and increasing the volume, speed and delivery of UK’s performance, in conjunction with NIHR and regional bodies such as AHSNs.
   3. Identify where the revisions to European legislation due to be implemented in 2016/17 will have most benefit and where there are still areas to be addressed.
   4. Define and evaluate the opportunities for further administrative action in the UK and future EMA/EU legislative action, and the implications of any other action at either level for the clinical trials process in the UK.
3. **Real World Data**.
   1. Segment the various sources of real world data/evidence of relevance to clinical development and evaluation.
   2. Identify the opportunities, constraints and practicalities of the use of such real world data in an accelerated pathway, in providing evidence to payers of product cost-effectiveness and to innovators to support future NICE assessments
   3. Identify the extent to which the existing infrastructure delivers the data required.
   4. This work should work closely with the ongoing IMI GetReal project, the GSK Salford project, CPRD, HSCIC etc.
4. **Ethics and communications**.
   1. Identify the patient ethics and communications issues of adaptive development
   2. Consider the relative ‘risk appetite’ of patients versus clinicians
   3. Recommend ways in which these issues might be addressed to facilitate adaptive development
5. **Prescribing controls**.
   1. Identify and define in what circumstances and by what means prescribing should be controlled at the point of early conditional licensing

The use of specific case examples is encouraged, particularly where products have experienced accelerated development within the current framework, identifying the lessons from such experience.

**Further detail**

* The contractor will report to the OLS project manager and will work closely with the workstream 2 champion; the workstream 2 Review lead and with others involved in the Review (such as those heading workstreams 1 and 3), to provide workstream 2 with timely and well-evidenced recommendations.
* It should be noted that work packages outlined above will be sequenced and prioritised by agreement with the project manager and workstream leadership as the project proceeds.
* The focus of this work should be on transformational new types of products that will come onto the market in the next decade; in particular stratified medicines and their partner diagnostics, convergent and combinatorial technologies and new therapeutic technologies. It may be appropriate to develop “archetypes” of future products
* The work should take into account the concurrent evaluation of the [Early Access to Medicines Scheme](https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams) (EAMS), NHS England’s [Evaluation through Commissioning](http://www.england.nhs.uk/tag/commissioning-through-evaluation/) pilot, the EMA’s [Adaptive Pathways](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp) and evaluation programmes considered by NICE, such as ‘coverage with evidence development’. It should note the extent to which these schemes currently fit together and the scope for them to be further developed/scaled up and integrated.
* The work should include primary research via a range of stakeholders, likely to include ALBs, industry, academia, key NHS Trusts, third sector, to identify the key issues for each of medicines, devices and diagnostics. It should also draw on evidence already collected by the Review from trade bodies, companies and other organisations. The Review team can help identify key contacts in a range of stakeholders if necessary.
* It should identify differences and overlaps in the processes for medicines, devices and diagnostics, and classes within them;
* Archetypal medicines /devices/diagnostics may be used to explore opportunities in more detail and highlight key barriers and issues.
* End products will need to be clear where issues and options are UK-wide or England-only, and where decisions are made or standards set at a European level.
* For the options under HMG/ALB influence, their applicability to emerging and future products e.g. stratified medicines and their partner diagnostics, and new therapeutic technologies should be noted.
* The AAR has developed a crowdsourcing platform where we are asking a broad range of stakeholders (clinicians, patients, industry, academia, government and regulatory bodies and more) to provide thoughts on the review questions for all the different work streams. The idea is to evolve the content on the platform as our thinking develops to have an ongoing conversation with our stakeholders. If appropriate, we would encourage you to use this platform to gather evidence and research for this work and test and refine ideas with our stakeholders. At a minimum we would expect to publish outputs from this work on this platform and invite comment from stakeholders. <https://engage.dh.gov.uk/acceleratedaccess/>

**Deliverables:**

* Clear factual evidence on both the status quo and the potential for improvement via the options for change being identified
* Analysis of options, including:
  + rationale for and prioritisation of potential changes:
  + costs or other impacts of change
  + where HMG has the strongest levers
* A list of stakeholders (individuals and organisations) consulted.
* Copy of methodology / evidence weighting and evaluation processes so the team can understand the basis for the evidence presented

**Delivery model:**

The anticipated timeframe for delivery is ten to twelve weeks. We expect the work to draw primarily upon stakeholder expertise, but it may also include some literature review. Regular meetings will be held with the workstream 2 team (minimum every 2 weeks, with a weekly update). At these meetings, there will be discussion of the options for change being considered by the Review and the evidence necessary to evaluate them. The outputs will initially be delivered to the project manager and workstream leaders but presentation may also be required to other leaders and members of the Review. The contractors may be asked to support the Review team in developing materials for and potentially participating in, workstream 2 workshops.

This work will be delivered in parallel with a review of EAMS and the contractor will be expected to work closely with that team. It is possible that one contractor may deliver both pieces of work, in which case we would expect to see significant efficiencies from such a delivery arrangement.

Analytical work for other workstreams within the Review is also being tendered. Collaboration between these different workpackages is expected, which the Review team will facilitate.

1. Authority Responsibilities

The DH will appoint a representative from the Office for Life Sciences (OLS), to act as the contract manager.

The workstream 2 team will meet regularly with the contractor to support the contractor to deliver the outputs of the ITT.

1. Contractor Responsibilities

• Appoint a Contract Manager to oversee the work and liaise with / report as DH requires to DH’s Contract Manager;

• Provide weekly activity reports and attend (minimum) fortnightly liaison meetings, or “as and when required by the Authority’s Project Manager;

• Pro-actively advise of any issues affecting progress against the KPIs

• Perform quality assurance on all aspects of the programme;

• Provide the Authority with timely and ongoing evaluation and quality assurance information relating to the programme; and

• Provide on a monthly basis updates on costs.

• Attend a post contract review with the Authority to review whether the objectives of the contract were met, to review the benefits achieved and to identify any lessons learnt for future projects.

1. Contract Management and Monitoring

The minimum key performance indicators (KPI’s) to be used to measure the success of this Contract are:

1. provision of the deliverables by the agreed target dates;

|  |  |
| --- | --- |
| **Indicator** | **Due date** |
| Regular progress updates to project manager and wider team | Weekly |
| Regular meetings with the project manager and wider team | Minimum fortnightly |
| Broad stakeholder engagement:   * List of individuals and organisations approached and who commented provided to review team * Good diversity of stakeholders at workshops to test and validate emerging findings | Lists to be shared in regular updates and the draft and final reports. |
| Summary report to feed in to the October interim report for the overall Review | September (date tbc) |
| Draft report provided for comment | 6 November |
| Final Word report and PowerPoint summary including clear evidence of the impact of current flexibilities and potential for improvements, incorporating:   * strengths and weaknesses of current processes; * an assessment of the degree to which these processes are future-proofed * assessment of any priority areas for change.   Supporting evidence and data supplied in Annexes. | 24 November |
| Close off meeting | December |

1. payments to be made in arrears on completion of the project, based on achievement of all milestones, against the agreed deliverables; through-out the Contract Period.
2. accurate and timely invoicing.
3. TIMETABLE

The project is expected to take up-to ten to twelve weeks and will be completed by 30 November 2015, unless extended by agreement.

Payment will be in arrears but is dependent on the successful completion of all outputs described above through-out the Contract period.

1. SKILLS AND KNOWLEDGE TRANSFER

It is vital to ensure that all skills and knowledge gained by this requirement are retained by the DH and the Review team for the longer term. It is expected that the contractor will provide electronic and hard copies of all reports, work closely with DH staff continuously throughout the work to ensure the effective transfer of knowledge. The contractor will be expected to organise and facilitate lessons learned sessions between the Review team and the Contractor.

**Schedule One (a): Tenderer Response**

1. Organisation details

**Tenderer name**

Please confirm the name of the Tenderer\*:

|  |  |
| --- | --- |
| **Tenderer Name:** |  |

* Full name of organisation tendering (or of organisation acting as the lead contact where a consortium bid is being submitted)

**Contact details\***

Tenderers must provide contact details for this tender.

|  |  |
| --- | --- |
| **Contact Name\*** |  |
| **Telephone number** |  |
| **Email address:** |  |
| **Address:** |  |

* Contact is the person responsible for any queries relating to this proposal

**Organisational status**

Please confirm whether (or not) the Tenderer is a Small & Medium Enterprise[[1]](#footnote-1) (**SME**).

|  |  |
| --- | --- |
| **The Tenderer is an SME (Yes / No)** |  |

1. **Solution Proposal** - - refer to table 2, Part A for evaluation intention and evaluation criteria.

* **Overview**

Tenderers must provide a concise summary highlighting the key aspects of the proposal.

(This response is not evaluated and should be used to contextualise the Tenderer’s response.)

| **Response (maximum 500 words)** |
| --- |
| **Our understanding of your requirements** |

* **Leadership (10%)**

Provide details of the qualifications and skills of the individual whose responsibility will be to ensure that the requirement is delivered.

| **Response (maximum 500 words)** |
| --- |
|  |

* **Method statement (35%)**

Describe (with specific reference to the elements of the requirements and the outcomes expected) how it is intended to deliver the requirements of the specification.

| **Response (maximum 1500 words)** |
| --- |
|  |

* **Resource Plan (20%)**

Provide a complete resource plan for the delivery of the Specification including details of the team involved, what these individuals will be doing and why these individuals are suitable for this requirement.

| **Response (maximum 1000 words)** |
| --- |
|  |

* **Exit Strategy & Skills Transfer (5%)**

Describe the processes and deliverables of the exit phase of the service and how skills will be retained within the Authority.

| **Response (maximum 500 words)** |
| --- |
|  |

* **SME and sustainability outcome reporting (This question is not weighted)**

Briefly describe how you are able to satisfy / commit to the Government initiativeson SME expenditure and sustainability outcome reporting

| **Response (maximum 200 words)** |
| --- |
|  |

1. Pricing Schedule
2. General Instructions
   1. The rates contained within the Pricing Schedule are, unless otherwise expressly agreed between the parties, firm.
   2. The rates entered shall be deemed to include complete provision for full compliance with the requirements of the Contract.
   3. **The rates exclude VAT**.
   4. The rates entered in the Pricing Schedule shall include all travel and subsistence costs. Expenses will only be approved if supported by original receipts. The Authority will only pay for expenses claimed that are in line with the Department’s guidelines for expenses. Original receipts will need to be provided.
   5. The Authority will only make payment for overnight stays that have been authorised beforehand in writing by the Authority's Representative.
   6. Any extra expenses other than travel and subsistence must be priced separately in the Pricing Schedule. The Department will only pay for expenses claimed that are included in this pricing schedule and are deemed to be reasonable for delivery of the requirement.
   7. Tenderers must include in the pricing schedules any discounts or any reduced pricing they are proposing to offer to the Authority in delivery of this requirement.

|  |  |  |  |
| --- | --- | --- | --- |
| **DESCRIPTION OF SERVICE** | | | **FIRM PRICE** |
| Management & staff and respective man-days: | | | |
| Name & Position | Cost per day | No of days |  |
| (a) | £ |  | £ |
| (b) | £ |  | £ |
| (c) | £ |  | £ |
| (d) | £ |  | £ |
| (e) | £ |  | £ |
| Sub-total/total consultancy cost | | | £ |
| Production of reports *(or any other output)* | | | £ |
| Any other costs (please describe what these costs are) | | | £ |
|  | | | £ |
| **Total Contract Price (Evaluation Price)** | | | £ |

**Schedule three: Contract Monitoring**

* + - 1. **General Instructions**
  1. Tenderers must provide all the information requested in the following section as part of their tender proposal. Supporting documents may be submitted but must be clearly referenced back to the appropriate section.

1. **Representatives**
   1. Name of Authority's Representative(s): To be confirmed at Contract award
   2. Name of Contractor's Representative(s): **xxxxx**
2. **Deliverables**
   1. To be completed (in line with section Two – the requirement)

**Key performance indicators**

|  |  |
| --- | --- |
| **Indicator** | **Due date** |
| Regular progress updates to project manager and wider team | Weekly |
| Regular meetings with the project manager and wider team | Minimum fortnightly |
| Broad stakeholder engagement:   * List of individuals and organisations approached and who commented provided to review team * Good diversity of stakeholders at workshops to test and validate emerging findings | Lists to be shared in regular updates and the draft and final reports. |
| Summary report to feed in to the October interim report for the overall Review | September (date tbc) |
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| Close off meeting | December |

1. **Meetings**
   1. Frequency of contract management meetings: Fortnightly
   2. Location of contract management meetings: Face to face in London or telephone/video conference as agreed as appropriate
   3. Checking performance against anticipated plan: Weekly status reports will be expected and used to inform the contract management meetings
2. **Remedies**
   1. Where the Authority through contract management meetings identifies issues of below expected performance the contractor shall work with the Authority to ensure that such performance is addressed and the delivery outputs and timescales are adhered to. Where performance issues arise the Supplier shall address with the Authority immediately to resolve, with the supplier setting out how such matters will be dealt with to ensure continued delivery to the required standard.

Schedule Four: Confidential & Commercially Sensitive Information

1. General
   1. All the information that the Authority supplies as part of this Contract may be regarded as Confidential Information as defined in Condition 1 (Definitions) of Section Three – Conditions of Contract.
   2. The Contractor considers that the type of information listed in paragraph 2.1 below is Confidential Information.
   3. The Contractor considers that the type of information listed in paragraph 2.2 below is Commercially Sensitive Information.
2. Types of Information that the Contractor Considers to be Confidential
   1. Type 1: Confidential information:

|  |  |  |
| --- | --- | --- |
| Information considered confidential | Reason for FoIA exemption  (Include paragraph reference) | Period exemption is sought (Months) |
| None |  |  |
|  |  |  |

* 1. Type 2: Commercially sensitive information:

|  |  |  |
| --- | --- | --- |
| Information considered commercially sensitive | Reason for FoIA exemption  (Include paragraph reference) | Period exemption is sought (Months) |
| None |  |  |
|  |  |  |

Schedule Five: Administrative Instructions

1. Authorisation
   1. The person shown below person shall act as the Authority's Representative on all matters relating to the Contract:

|  |  |
| --- | --- |
| Name | **To be confirmed at Contract Award** |
| Contact Details | **To be confirmed at Contract Award** |

* 1. The Department's Representative may authorise other officers to act on their behalf.

1. Notices
   1. Any notice the Contractor wishes to send the Authority shall be sent in writing to the Authority's Representative at the address shown in paragraph 1.1 above.
   2. Any notice the Authority wishes to send the Contractor shall be sent in writing to the Contractor's Representative at the address shown in paragraph 4.2 below.
2. Address for Invoices
   1. It is preferred that invoices are sent electronically to:

[MB-PaymentQueries@dh.gsi.gov.uk](mailto:MB-PaymentQueries@dh.gsi.gov.uk)

* 1. Alternatively invoices can be sent to the Department addressed to:

Department of Health

Accounts Payable

Room 530

Richmond House

79 Whitehall

London

SW1A 2NS

* 1. Invoices must not be sent to the Authority's Representative.

1. Correspondence
   1. All correspondence to the Authority except that for or relating to invoices shall be sent to the following address: *To be confirmed at contract award stage*
   2. All correspondence to the Contractor shall be sent to the following address:

**Tenderer to provide Address**

**Schedule Five: Appendix A: Variation to Contract**

**(FOR INFORMATION ONLY – NOT FOR COMPLETION AT TENDER STAGE)**

|  |  |
| --- | --- |
| Contract Title: |  |

|  |  |
| --- | --- |
| For the Provision of: |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Contract Ref: |  | Variation No: |  | Date: |  |

BETWEEN:

The Secretary of State for Health (hereinafter called the Department) and [INSERT NAME OF CONTRACTOR] (hereinafter called the Contractor) having his main or registered office at [DN:INSERT ADDRESS]:

The Contract is varied as follows:

(DN:INSERT DETAILS OF VARIATION)

Words and expressions in this Variation shall have the meanings given to them in the Contract.

The Contract, including any previous Variations, shall remain effective and unaltered except as amended by this Variation.

SIGNED:

|  |  |  |  |
| --- | --- | --- | --- |
| For: The AUTHORITY |  | For the Contractor |  |
| By |  | By |  |
| Full name |  | Full name |  |
| Grade / Pay Band |  | Title |  |
| Date |  | Date |  |

**Schedule Five: Appendix B: Novation Agreement**

**(FOR INFORMATION ONLY – NOT FOR COMPLETION AT TENDER STAGE)**

THIS DEED (THIS AGREEMENT is made on the [dd] day of [month & year] BETWEEN

(1) THE SECRETARY OF STATE FOR HEALTH (the **Secretary of State**) whose principal place of business is at Richmond House, 79 Whitehall, London, SW1A 2NS,

(2) THE [CONTRACTOR] of [address]

(3) THE [NEW PARTY] of [address]

WHEREAS

(A) This Agreement is supplemental to an agreement dated [dd Month Year] between the Secretary of State and the Contractor (the **Contract**) under which the Contractor agreed to provide services to the Secretary of State.

(B) The Secretary of State has authorised the New Party to replace the Secretary of State as the contracting Department under the Contract on the terms of this Agreement and the Contractor is willing to accept the New Party in place of the Secretary of State on those terms.

IT IS HEREBY AGREED AS FOLLOWS:

1. Subject to the following Clauses of this Agreement –

a) The Contract shall continue in full force and effect as if the New Party were named as a party to the Contract in place of the Secretary of State for Health.

b) All rights, obligations and liabilities arising under the Contract from the date of this Agreement shall be rights, obligations and liabilities between the New Party and the Contractor.

c) Any existing rights, obligations or liabilities of the Secretary of State relating to the performance of the Contract up to the date of this Agreement shall pass to the New Party and shall be enforceable between the Contractor and the New Party in place of the Secretary of State.

2. The rights, obligations and liabilities of the Contract shall be exercisable and enforceable as the rights of the New Party under this Agreement.

3. This Agreement shall be governed by and interpreted in accordance with English law and shall be subject to the jurisdiction of the courts of England.

Signed by ....................................for and on behalf of the

Secretary of State for Health in the presence of:

Signed by ....................................for and on behalf of the

Contractor in the presence of:

Signed by ....................................for and on behalf of the

New Party in the presence of:

**Schedule Five: Appendix C: Sub-Contractors**

All suppliers to the Department of Health are asked to provide details of all sub-contractors that will be used to perform the contract.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name & Address of Sub-Contractor | | Service performed for Contractor | Provide details of staff numbers[[2]](#footnote-2) | Provide latest year’s turnover |
| Name: | N/a |  |  |  |
| Address: |  |
| Name: |  |  |  |  |
| Address: |  |
| Name: |  |  |  |  |
| Address: |  |

Schedule Six: Form of Tender

Declaration

Declaration

PROPOSAL FOR THE PROVISION OF Accelerated Access Review (AAR) – a review of adaptive pathways (workstream 2)

Having examined the proposed Contract comprising of:

(a) Part A – Section Two, (Conditions of Contract);

(b) Part B – Schedules One, One (a), Two and Six (mandatory); and

(c) Part B – Schedules Three to Five inclusive (as amended).

As enclosed in the ITT response dated (INSERT DATE). We do hereby tender against the requirements, and terms and conditions of the proposed Contract.

We undertake to keep the tender open for acceptance by the Authority for a period of ninety (90) days from the deadline for receipt of tenders.

We declare that this is a bona fide tender, intended to be genuinely competitive, and that we have not fixed or adjusted the amount of the tender by, or under, or in accordance with, any agreement or arrangement with any other person. We further declare that we have not done, and we undertake that we will not do, any of the following acts prior to award of this Contract:

(a) Collude with any third party to fix the price of any number of tenders for this Contract;

(b) Offer, pay, or agree to pay any sum of money or consideration directly or indirectly to any person for doing, having done, or promising to be done, any act or thing of the sort described herein and above.

Unless and until the Tenderer and the Authority have executed a formal agreement, the Authority's acceptance of this tender with all its enclosures shall not constitute a binding contract between us. We understand that you are not bound to accept the lowest price, or any, tender.

Name of person duly authorised to sign tenders:

Date: ..........................................

Name: ..........................................

in the capacity of: ................................................................

duly authorised to sign tenders for and on behalf of:

............................................................................

By completing this Declaration and submitting your tender you have agreed that the statements in this Form of Tender are correct.

1. To be considered an SME, an organisation must have a headcount less than 250 Annual Work Units (anyone that has worked full-time within the enterprise, or on its behalf, during the reference year counts as one unit. Part-time staff, seasonal workers and those who did not work the full year are treated as fractions of one unit) **AND** a turnover less than €50 million **OR** annual balance sheet of €48 million. [↑](#footnote-ref-1)
2. This is the average annual numbers of both staff and managerial staff employed over the last trading year [↑](#footnote-ref-2)