

This notice in TED website: <http://ted.europa.eu/udl?uri=TED:NOTICE:8408-2016:TEXT:EN:HTML>

**United Kingdom-Potters Bar: Graphic design services
2016/S 007-008408**

Contract notice

Services

Directive 2004/18/EC

Section I: Contracting authority

I.1) Name, addresses and contact point(s)

Medicines and Healthcare products Regulatory Agency

Blanche Lane, South Mimms

Contact point(s): Procurement

EN6 3QG Potters Bar

UNITED KINGDOM

Telephone: +44 1707641000

E-mail: purchasing@nibsc.org

Internet address(es):

General address of the contracting authority: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Address of the buyer profile: www.mhra.gov.uk

Electronic access to information: <https://phe.bravosolution.co.uk>

Electronic submission of tenders and requests to participate: <https://phe.bravosolution.co.uk>

Further information can be obtained from: The above mentioned contact point(s)

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from: The above mentioned contact point(s)

Tenders or requests to participate must be sent to: The above mentioned contact point(s)

I.2) Type of the contracting authority

National or federal agency/office

I.3) Main activity

Health

I.4) Contract award on behalf of other contracting authorities

Section II: Object of the contract

II.1) Description

II.1.1) Title attributed to the contract by the contracting authority:

MHRA — CAMD — Competent Authorities for Medical Devices Project Website.

II.1.2) Type of contract and location of works, place of delivery or of performance

Services

Service category No 7: Computer and related services

Main site or location of works, place of delivery or of performance: Medicines and Healthcare Products Regulatory Agency, 5th floor, 151 Buckingham Palace Road, London, SW1W 9SZ, United Kingdom.

NUTS code UKI

II.1.3) Information about a public contract, a framework agreement or a dynamic purchasing system (DPS)

The notice involves a public contract

II.1.4) Information on framework agreement

Estimated total value of purchases for the entire duration of the framework agreement

Estimated value excluding VAT: 1 EUR

II.1.5) Short description of the contract or purchase(s)

This questionnaire has been issued by the Medicines and Healthcare Products Regulatory Agency, also referred to as 'the Agency') on behalf of the Competent Authorities for Medical Devices (CAMD) project. The CAMD network is an umbrella under which the national competent authorities in the EU, and associated parties to the system (European Free Trade Association (EFTA) and Turkey), work to enhance the level of collaborative work in what is a single market for medical devices.

Competent authorities have specific responsibilities for market surveillance and other activity under the terms of the legislation. The governance for the network was changed in 2014 to incorporate an elected executive. The executive was charged with developing better collaboration with the European Commission to improve both strategic planning and the distribution of work across both Commission-led and CAMD-led working groups. The Dalli plan set out 3 challenges: enhance collaborative working; improve market surveillance; and better communication. Subsequently, the CAMD network has initiated 2 Joint Action projects which are designed to help the member states deliver on these commitments, and develop better mechanisms for working together and sharing workload:

— The 1st concerns the quality of instructions for use of re-sterilisable surgical instruments and is led by the Austria competent authority. This started in November 2015 and is due to be completed by December 2017.

The 2nd concerns market surveillance of medical devices which is more expansive and led by the UK competent authority (Medicines and Healthcare products Regulatory Agency). This, subject to agreement, will run from autumn 2016 to autumn 2019.

II.1.6) Common procurement vocabulary (CPV)

79822500, 72212325, 72413000, 72212300

II.1.7) Information about Government Procurement Agreement (GPA)

The contract is covered by the Government Procurement Agreement (GPA): yes

II.1.8) Lots

This contract is divided into lots: no

II.1.9) Information about variants

II.2) Quantity or scope of the contract

II.2.1) Total quantity or scope:

To provide a website that:

— Incorporates the information and communication requirements of the CAMD and current and future Joint Action projects to stakeholders;

— Has strong linkage to the EU Commission website to enhance stakeholder's ability to navigate the regulatory landscape and locate appropriate organisations and information;

— Is an asset to stakeholders in all participating member states, enhancing engagement and transparency.

b) Audiences:

The audiences for the website are varied:

— CAMD partners (key people who are working on the Joint Action project via 1 or more of its major groups);

- Devices regulatory staff working in Competent Authorities (CA) across all EU member states and the European Economic Area (EEA);
- Industry — trade groups and professional bodies across EU member states and the EEA;
- Industry — manufacturers of medical devices across EU member states and the EEA;
- Healthcare professionals across all EU member states and the EEA;
- Patients across all EU member states and the EEA;
- Media across all EU member states and the EEA.

c) Content:

Content will be developed and provided to the supplier by the CAMD project team at appropriate points in the project development. See Ideal / indicative project timetable.

d) Language:

The website will be in English but we would want to consider including a free ware translate function or design so that can be effectively translated by Google, etc.

e) Content management system (CMS):

The supplier will build the site in open source, using an easy-to-use CMS. We are assuming there would be no licence fee if written in open source. Once the website is built the CAMD project team will take over content management. A number of project managers will need access from various member states to upload and update information.

The supplier will provide reasonable training and ongoing support in the use of the CMS for the duration of the project (to 31.12.2019).

f) Responsive design:

The website should be optimised for use across a range of devices, browsers and operating systems.

Ongoing website maintenance:

The supplier will maintain the site and make reasonable updates during the project lifespan (to autumn 2019) through an agreed number of ad hoc development days included in the contract. Significant additional changes within the lifespan will be subject to separate negotiation and agreement.

h) Website and content ownership:

All content, the website and IPR is owned by CAMD's sponsoring agencies and the European Commission.

i) Timing:

The website should be in place and in use before the end of April 2016 (Beta version) with a finished site ready no later than July 2016.

j) Accessibility:

The website and its content needs to meet industry standards for accessibility for example Level AA of the Web Content Accessibility Guidelines (WCAG) 2.0.

k) Design style guidelines:

We currently have a logo and are commissioning a basic style guide that will be available to suppliers.

l) Hosting:

We require the supplier to host the website on a secure server that meets recognised industry standards for the duration of the project (to 31.12.2019).

Estimated value excluding VAT: 1 EUR

II.2.2) **Information about options**

II.2.3) **Information about renewals**

This contract is subject to renewal: no

II.3) **Duration of the contract or time limit for completion**

Duration in months: 48 (from the award of the contract)

Section III: Legal, economic, financial and technical information

III.1) Conditions relating to the contract

III.1.1) Deposits and guarantees required:

Participants will be advised if this is necessary during the procurement. Parent company and/or other guarantees of performance and financial liability may be required by the agency if considered appropriate.

III.1.2) Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them:

Please see the tender documentation.

III.1.3) Legal form to be taken by the group of economic operators to whom the contract is to be awarded:

1 member of any grouping / consortium of suppliers will be required to accept prime contractorship.

III.1.4) Other particular conditions

III.2) Conditions for participation

III.2.1) Personal situation of economic operators, including requirements relating to enrolment on professional or trade registers

Information and formalities necessary for evaluating if the requirements are met: Under the Public Contracts Regulations 2015 Regulation 57 (1), potential suppliers will be excluded the procurement process if there is evidence of convictions relating to:

- Conspiracy within the meaning of section 1 or 1A of the Criminal Law Act 1977 (a) or article 9 or 9A of the Criminal Attempts and Conspiracy (Northern Ireland) Order 1983 (b) where that conspiracy relates to participation in a criminal organisation as defined in Article 2 of Council Framework Decision 2008/841/JHA on the fight against organised crime (c);
- Corruption within the meaning of section 1 (2) of the Public Bodies Corrupt Practices Act 1889 (d) or section 1 of the Prevention of Corruption Act 1906 (e);
- The common law offence of bribery;
- 'Bribery within the meaning of sections 1, 2 or 6 of the Bribery Act 2010 (f), or section 113 of the Representation of the People Act 1983 (g);'
- 'Where the offence relates to fraud affecting the European Communities' financial interests as defined by Article 1 of the Convention on the protection of the financial interests of the European Communities (h):
 - (i) The common law offence of cheating the Revenue;
 - (ii) The common law offence of conspiracy to defraud;
 - (iii) Fraud or theft within the meaning of the Theft Act 1968 (i), the Theft Act (Northern Ireland) 1969 (j), the Theft Act 1978 (k) or the Theft (Northern Ireland) Order 1978 (l);
 - (iv) Fraudulent trading within the meaning of section 458 of the Companies Act 1985 (m), article 451 of the Companies (Northern Ireland) Order 1986 (n) or section 993 of the Companies Act 2006 (o);
 - (v) Fraudulent evasion within the meaning of section 170 of the Customs and Excise Management Act 1979 (p) or section 72 of the Value Added Tax Act 1994 (q);
 - (vi) An offence in connection with taxation in the European Union within the meaning of section 71 of the Criminal Justice Act 1993 (r);
 - (vii) Destroying, defacing or concealing of documents or procuring the execution of a valuable security within the meaning of section 20 of the Theft Act 1968 (s) or section 19 of the Theft Act (Northern Ireland) 1969 (t);
 - (viii) Fraud within the meaning of section 2, 3 or 4 of the Fraud Act 2006 (u); or
 - (ix) The possession of articles for use in frauds within the meaning of section 6 of the Fraud Act 2006, or the making, adapting, supplying or offering to supply articles for use in frauds within the meaning of section 7 of that Act;'

— 'Any offence listed —

(i) In section 41 of the Counter Terrorism Act 2008 (a); or

(ii) In Schedule 2 to that Act where the court has determined that there is a terrorist connection;'

— Any offence under sections 44 to 46 of the Serious Crime Act 2007 (b) which relates to an offence covered by subparagraph (f);

Money laundering within the meaning of sections 340 (11) and 415 of the Proceeds of Crime Act 2002 (c);

An offence in connection with the proceeds of criminal conduct within the meaning of section 93A, 93B or 93C of the Criminal Justice Act 1988 (d) or article 45, 46 or 47 of the Proceeds of Crime (Northern Ireland) Order 1996 (e);

— An offence under section 4 of the Asylum and Immigration (Treatment of Claimants, etc.) Act 2004 (f);

— An offence under section 59A of the Sexual Offences Act 2003 (g);

— An offence under section 71 of the Coroners and Justice Act 2009 (h);

— An offence in connection with the proceeds of drug trafficking within the meaning of section 49, 50 or 51 of the Drug Trafficking Act 1994 (i); or

— 'Any other offence within the meaning of Article 57 (1) of the Public Contracts Directive —

(i) As defined by the law of any jurisdiction outside England and Wales and Northern Ireland; or

(ii) Created, after the day on which these Regulations were made, in the law of England and Wales or Northern Ireland.'

— 'Under the Public Contracts Regulations 2015 regulations 57 (3) an economic operator shall be excluded from participation in a procurement procedure where the following circumstances apply.

(a) Economic operator is in breach of its obligations relating to the payment of taxes or social security contributions; and

(b) The breach has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of any of the jurisdictions of the United Kingdom.

Exceptions may be considered if the economic operator has fulfilled its obligations by paying, or entering into a binding arrangement with a view to paying, the taxes or social security contributions due, including, where applicable, any interest accrued or fines. Use this question to explain any answers of yes above.

The Authority is will exclude you from consideration if any of the following apply without good reason or explanation. Where the economic operator is bankrupt or is the subject of insolvency or winding up proceedings, where its assets are being administered by a liquidator or by the Court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under the laws and regulations of any State;

The economic operator is guilty of grave professional misconduct, which renders its integrity questionable;

The economic operator has entered into agreements with other economic operators aimed at distorting competition;

'Where a conflict of interest within the meaning of regulation 24 cannot be effectively remedied by other, less intrusive, measures;

Regulation 24:

24 — (1) Contracting authorities shall take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of procurement procedures so as to avoid any distortion of competition and to ensure equal treatment of all economic operators.

(2) For the purposes of paragraph (1), the concept of conflicts of interest shall at least cover any situation where relevant staff members have, directly or indirectly, a financial, economic or other personal interest which might be perceived to compromise their impartiality and independence in the context of the procurement procedure.

(3) In paragraph (2)— ‘Relevant Staff Members’ means staff members of the contracting authority, or of a procurement service provider acting on behalf of the contracting authority, who are involved in the conduct of the procurement procedure or may influence the outcome of that procedure; and ‘Procurement Service Provider’ means a public or private body which offers ancillary purchasing activities on the market.’

‘Where a distortion of competition from the prior involvement of the economic operator in the preparation of the procurement procedure, as referred to in regulation 41, cannot be remedied by other, less intrusive, measures;

Regulation 41:

(1) Where a candidate or tenderer, or an undertaking related to a candidate or tenderer;

(a) Has advised the contracting authority, whether in the context of regulation 40 or not, or

(b) Has otherwise been involved in the preparation of the procurement procedure, the contracting authority shall take appropriate measures to ensure that competition is not distorted by the participation of that candidate or tenderer.’

‘Where the economic operator has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity, or a prior concession contract, which led to early termination of that prior contract, damages or other comparable sanctions;

‘Where the economic operator —

(i) Has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria; or

(ii) Has withheld such information or is not able to submit supporting documents required under regulation 59; or’

‘Where the economic operator has —

(i) Undertaken to —

(aa) Unduly influence the decision-making process of the contracting authority; or

(bb) Obtain confidential information that may confer upon it undue advantages in the procurement procedure; or

(ii) Negligently provided misleading information that may have a material influence on decisions concerning exclusion, selection or award.’

The agency reserves the right to use its discretion to exclude a supplier where it can demonstrate the supplier’s non-payment of taxes/social security contributions where no binding legal decision has been taken. This section only applies where the agency has indicated that the contract is over 5 000 000 GBP in value. ‘Occasion of Tax Non-Compliance’ means:

(a) — Any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1.10.2012 is found to be incorrect as a result of:

(a) 1 — A Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle;

(a) 2 — The failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or

(b) The Supplier’s tax affairs give rise on or after 1.4.2013 to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a penalty for civil fraud or evasion.

III.2.2) **Economic and financial ability**

Information and formalities necessary for evaluating if the requirements are met: Under regulation 58 of the Public Contracts Regulation 2015 the agency will undertake an assessment of your organisation’s economic

and financial standing. You will be contacted by the agency if this assessment identifies that a parent or other type of guarantee is required. You will need to provide 1 of the following set out below (Regulation 60 (6) Public Contracts Regulations 2015:

- i) A copy of your audited accounts for the 2 most recent years;
- ii) A statement of your turnover, profit and loss account and cash flow for the most recent year of trading;
- iii) A statement of your cash flow forecast for the current year and a bank letter outlining the current cash and credit position;
- iv) Alternative means of demonstrating financial status if trading for less than a year.

III.2.3) Technical capacity

Information and formalities necessary for evaluating if the requirements are met:

The agency may assess the past performance of a Supplier (through a Certificate of Performance provided by a Customer or other means of evidence). The authority may take into account any failure to discharge obligations under the previous principal relevant contracts of the Supplier. The agency may also assess whether specified minimum standards for reliability for such contracts are met. In addition, the agency may re-assess reliability based on past performance at key stages in the procurement process (i.e. supplier selection, tender evaluation, contract award stage etc.). Suppliers may also be asked to update the evidence they provide in this section to reflect more recent performance on new or existing contracts (or to confirm that nothing has changed).

III.2.4) Information about reserved contracts

III.3) Conditions specific to services contracts

III.3.1) Information about a particular profession

III.3.2) Staff responsible for the execution of the service

Section IV: Procedure

IV.1) Type of procedure

IV.1.1) Type of procedure

Open

IV.1.2) Limitations on the number of operators who will be invited to tender or to participate

IV.1.3) Reduction of the number of operators during the negotiation or dialogue

IV.2) Award criteria

IV.2.1) Award criteria

The most economically advantageous tender in terms of the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document

IV.2.2) Information about electronic auction

An electronic auction will be used: no

IV.3) Administrative information

IV.3.1) File reference number attributed by the contracting authority:

P2582

IV.3.2) Previous publication(s) concerning the same contract

no

IV.3.3) Conditions for obtaining specifications and additional documents or descriptive document

Time limit for receipt of requests for documents or for accessing documents: 8.2.2016 - 17:00

Payable documents: no

IV.3.4) Time limit for receipt of tenders or requests to participate

2.2.2016 - 17:00

IV.3.5) **Date of dispatch of invitations to tender or to participate to selected candidates**

IV.3.6) **Language(s) in which tenders or requests to participate may be drawn up**
English.

IV.3.7) **Minimum time frame during which the tenderer must maintain the tender**
Duration in months: 3 (from the date stated for receipt of tender)

IV.3.8) **Conditions for opening of tenders**

Section VI: Complementary information

VI.1) **Information about recurrence**

This is a recurrent procurement: no

VI.2) **Information about European Union funds**

The contract is related to a project and/or programme financed by European Union funds: yes

Reference to project(s) and/or programme(s): Funded by the Consumers, Health and Food Executive Agency (CHAFAEA) and with contributions from Member States involved.

VI.3) **Additional information**

This Framework will be available for the use of any SCOPE partners as listed on the SCOPE website: <http://www.scopejointaction.eu/partners/>

Suppliers Instructions: How to Express Interest in this Tender: 1. Register your company on the eSourcing portal (this is only required once): www.phe.bravosolution.co.uk and click the link to register — Accept the terms and conditions and click 'continue' — Enter your correct business and user details — Note the username you chose and click 'Save' when complete — You will shortly receive an email with your unique password (please keep this secure). 2. Express an Interest in the Tender — Login to the portal with the username/password — Click the 'PQQs / ITTs Open To All Suppliers' link. (These are Pre-Qualification Questionnaires or Invitations to Tender open to any registered supplier) — Click on the relevant PQQ/ ITT to access the content — Click the 'Express Interest' button at the top of the page — This will move the PQQ /ITT into your 'My PQQs/ My ITTs' page. (This is a secure area reserved for your projects only) — You can now access any attachments by clicking 'Buyer Attachments' in the 'PQQ/ ITT Details' box. 3. Responding to the Tender — Click 'My Response' under 'PQQ/ ITT Details', you can choose to 'Create Response' or to 'Decline to Respond' (please give a reason, if declining) — You can now use the 'Messages' function to communicate with the buyer and seek any clarification — Note the deadline for completion, then follow the onscreen instructions to complete the PQQ/ ITT — There may be a mixture of online and offline actions for you to perform (there is detailed online help available). You must then submit your reply using the 'Submit Response' button at the top of the page. If you require any further assistance, please consult the online help or contact the eTendering help desk.

Please note this is a Medicines and Healthcare Products Regulatory Agency procurement, however the procurement is being run through Public Health England's e-tendering portal.

VI.4) **Procedures for appeal**

VI.4.1) **Body responsible for appeal procedures**

VI.4.2) **Lodging of appeals**

VI.4.3) **Service from which information about the lodging of appeals may be obtained**

VI.5) **Date of dispatch of this notice:**
9.1.2016