



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Technical specifications for open invitation to tender

Procurement Procedure EMA/2013/06/PD
Document Delivery Services



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Technical specifications for open invitation to tender No. EMA/2013/06/PD – Document Delivery Services

1. Title of the invitation to tender

This document contains the Technical Specifications for the Open Invitation to Tender no. EMA/2013/06/PD – Document Delivery Services.

The contract notice for this open tender has been published in the Official Journal of the European Union No. S202 on 17 October 2013.

2. Objectives and context of the invitation to tender

The European Medicines Agency (“the Agency”) is a decentralised body of the European Union based in Canary Wharf in the Docklands area of London (E14). Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency was established in 1995 and operates under Council Regulation No 726/2004 to provide a system for the authorisation of medicinal products. The Agency is an Agency of the European Union and has its own legal personality. The Agency’s budget is subject to checks and audits by the Court of Auditors.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised marketing authorisation is valid in all European Union and EEA-EFTA states. The safety of medicines is monitored constantly by the Agency through a pharmacovigilance network.

The Agency also gives scientific advice and protocol assistance to companies for the development of new medicinal products. It publishes guidelines on quality, safety and efficacy testing requirements. A dedicated office provides special assistance to small and medium-sized enterprises (SMEs). Seven scientific committees, composed of members of all EU and EEA-EFTA states, some including patients’ and doctors’ representatives, conduct the main scientific work of the Agency.

The Agency’s Information Centre supports all staff in regards to their information needs. Its collection contains books, compendia, electronic books, journal subscriptions (print and electronic) and access to a variety of database resources.

3. Subject of the tender

The Agency considers that it may require document delivery services for the supply of articles from periodicals, journals, reviews, reports, conference proceedings, or similar products, in paper and/or electronic format and in compliance with copyright regulations.

The main purpose of the framework contract will be the purchase of document delivery from print and electronic sources through a supplier; i.e. the Agency will conclude up to a maximum of 3 short-form framework contracts in cascading order (please see section 11 for further details).

This tender is not intended for subscriptions to journals or other databases, nor is it intended for the delivery of free publications.

The Agency's Information Centre is currently using a single supplier for the all its document delivery needs. The annual purchase of documents through document delivery service is around 500 documents, but we foresee an increase in demand. The majority of documents purchased are journal articles delivered electronically and covering the following subjects (this list is not exhaustive):

- Epidemiology
- Geriatric medicines
- Health management
- Herbal medicines
- Medical specialities (e.g. rheumatology, endocrinology)
- Oncology
- Paediatric medicines
- Pharmacology
- Pharmacovigilance
- Social science
- Toxicology

Our requirements are as follows:

Area	Essential	Desirable
Content	Scientific, Technical & Medical (STM) Literature	Management, Law, ICT, Languages & Linguistics
Languages	English	EU Member State languages
Coverage	Last 25 years	Last 100 years
Searching	Simple search	Advanced search Expert search (Boolean operators)
Ordering	Online ordering platform	E-mail Fax
Processing	Immediate information on availability	Immediate information on cost and delivery time
Tracking	Report on order status	Administration platform for tracking of orders
Delivery Time	Standard delivery time (48-96 hours) Urgent delivery time (2-24 hours)	Immediate access

Area	Essential	Desirable
Format	Electronic documents delivered through a cloud solution on the publisher's website and in original colour	Electronic documents in Pdf format available for download on the Agency's computers and in original colour
Financial	Monthly invoice (paper and electronic)	Administration platform for financial tracking
Customer Support	A dedicated team responsible for the overall management of the contract and for the communication with the Agency	Appointment of a dedicated account manager
Customer Services	Mon-Fri 09h00 to 17h00 (GMT), except on the Agency's public holidays and the Contractor's public holidays	Accessible 24/7
Training	Provision of initial training on the use of the online system free of charge. The tenderer may propose a remote training.	Provision of follow-up training as required free of charge.

A 'scenario of documents' and instructions on how to demonstrate the capacity to supply at least 80% of the items specified together with their cost, is enclosed in Annex II.

4. Participation in the tender

4.1. Agreements on public procurement

Participation in the Agency's tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with Union in the field of public procurement under the conditions laid down in that agreement.

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

4.2. Subcontracting

If the tender envisages subcontracting any part of this contract, the following documents must be provided with the tender submission:

- (i) A document signed by the tenderer stating clearly the identity, roles, activities and responsibilities of subcontractor(s) and specifying the volume/proportion for each subcontractor.
- (ii) A letter of intent by each subcontractor stating its unambiguous undertaking to collaborate with the tenderer if it wins the contract and the extent of the resources that it will put at the tenderer's disposal for the performance of the contract.

(iii) If requested under points 12, 13 and 14 any documents regarding the exclusion and/or selection criteria for any subcontractors.

If such documents are not provided, the Agency shall assume that the tenderer does not intend subcontracting.

5. Additional documentation available to tenderers

Further information about the work of the Agency can be obtained on its website: <http://www.ema.europa.eu>.

6. Information visit

Not applicable.

7. Variants

Not applicable.

8. Estimated contract volume

For delivery of documents through a single service, the estimated annual contract volume is 40,000 Euro. This is an estimate only which is not binding on the Agency.

The total value of the separate orders under the framework contract will depend on the titles and quantities to be ordered by the Agency. It is not possible for the Agency to commit itself to ordering a specified volume of documents. The number of titles and copies that the Agency will order may vary depending on its actual needs.

9. Price

9.1. Currency of tender

Prices can be submitted in Euro (EUR) or in Pounds Sterling (GBP).

The costing sheet attached to these specifications must be used to submit a tender. For the purposes of evaluation and comparison of the prices in the tender, and to ensure equal treatment of Tenderers, prices shall be converted by using the European Central Bank exchange rate in force on the date of the deadline of submission of this tender.

Please note that any financial costing sheet must be submitted in separate binders or folders, which must be clearly labelled, and on a CD-ROM.

9.2. All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include delivery, etc). No expenses incurred in the performance of the services will be reimbursed separately by the Agency.

9.3. Price revision

Prices submitted in response to this tender shall be fixed and not subject to revision for purchase orders placed during the first year of performance of the framework contract.

From the beginning of the second year of performance of the framework contract, prices may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the framework contract became effective. Purchase orders shall be placed on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision.

This revision shall be determined by the Tenderer's terms and conditions which will form part of the framework contract.

Purchase orders shall be placed on the basis of the charges in force on the date on which they become effective. Such charges shall not be subject to revision.

9.4. Costs involved in preparing and submitting a tender

The Agency will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

9.5. Period of validity of the tender

Tenderers must enclose a confirmation that the tender (including prices) is valid for six months from the final date for submission of the tender.

9.6. Protocol on the Privileges and Immunities of the European Union

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

10. Payment arrangements

Payments under the Contract shall be executed only if the Contractor has fulfilled all its contractual obligations by the date on which the invoice is submitted, including specified deliverables.

11. Contractual details

The Agency wishes to conclude up to a maximum of 3 short-form framework contracts in cascading order for the provision of document delivery services, as described above, for an initial period of 2 years with the prospect of a renewal for two further years. A framework contract will establish the terms governing purchase orders to be awarded during a given period, in particular with regard to price. The Agency may also elect to sign a service level agreement with contractors. The framework contract shall incorporate the contractor's terms and conditions. The terms and conditions will prevail over the terms in the draft framework contract.

Should more than one framework contract be awarded, as and when required, the Agency will order titles from the first priority supplier. In the case where the first priority supplier is unable to meet the request within the time limit indicated in the purchase order, the Agency would be entitled to send the order to the second priority supplier and the first supplier would be considered unavailable.

A draft contract is attached to these Technical Specifications as Annex V. Tenderers must confirm acceptance of the draft contract and terms and conditions of the tender as part of their tender response.

Signature of the framework contract imposes no obligation on the Agency to order services. Only the implementation of the framework contract through purchase orders is binding for the Agency.

Each purchase order will contain details of deliverables and timelines for particular services to be provided.

12. Exclusion criteria

All tenderers and subcontractors shall provide a declaration on their honour, duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion as listed in Annex III.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex IV before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender and subcontractors.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case the tenderer shall declare on its honour that the documentary evidence has already been provided in a previous procurement procedure and confirm that no changes in its situation have occurred.

13. Selection criteria: financial and economic capacity

Requirements

Tenderers must be in a stable financial position and have the economic and financial capacity to perform the contract.

The documentation supplied in response to this section will be reviewed to assess the general financial health of the tenderer (or all tenderers in the case of joint tenders whereby a consolidated assessment shall be made) and parent companies where the parent company is providing a guarantee. In addition to verifying that the financial turnover meets the required minimum amounts, as listed above and in the Official Journal notice, the on-going economic capacity will be assessed including financial independence and liquidity.

Evidence required

The documents or information listed below must be presented as evidence of compliance with the economic and financial capacity. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors.

If the tenderer is a company and is otherwise required under the law of the State in which it is established to publish its accounts, the following information is requested:

1. Appropriate statements from banks or, where appropriate, evidence of relevant professional risk indemnity insurance;
2. Financial statement for the last two years for which accounts have been closed;
3. A statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last two financial years;
4. If the tenderer relies on the capacities of other entities (e.g. a parent company), a written undertaking on the part of those entities confirming that they will place the resources necessary for performance of the contract at the disposal of the tenderer for the period of the contract. In such case the Agency may require that the successful tenderer(s) and such entities are jointly liable for the execution of the contract.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to above in points 1, 2 and 3 if such evidence has been submitted to it for the purposes of another procurement procedure and if it still complies with the requirements of the Agency. If, for some exceptional reason which the contracting authority considers justified, the tenderer is unable to provide the documentation mentioned in points 1, 2 and 3, it may prove its economic and financial capacity by any other means which the contracting authority considers appropriate.

14. Selection criteria: technical and professional capacity

Requirements:

The criteria for this contract are:

- Authorisation of the tenderer to perform the contract under national law.
- Experience in dealing with clients of similar scale providing high quality service and expertise in the field of digitisation, copyright law, DRM/ERM.
- Measures established to ensure high quality of supplies and services to customers.
- Manpower capacity involved in customer services and document delivery.
- Proof of proportion of subcontracting, if intended.
- Proof of conformity with industry standards.

Tenderers must meet all of the above requirements.

Evidence required:

The documents or information listed below must be presented as evidence of compliance with these selection criteria. If subcontracting is envisaged, documentation must be provided in relation to any subcontractors.

- Authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation of entry in the VAT register.

- A list of the principal services provided in the past three years, with the sums, dates and recipients, public or private.
- A description of measures employed to ensure quality of supplies and services (i.e. cooperation agreements with publishers and/or copyright authorities, quality management for customer service).
- A statement of the average annual manpower involved in customer services and document delivery, whether or not belonging directly to the tenderer, in the last three years.
- An indication of the proportion of the contract which the applicant may intend to subcontract.
- Sample documents (i.e. digitised article of scientific journal, electronic article) proving the conformity with standards for electronic document delivery in force and quality standards for digitisation. The documents (up to 10 samples) may be provided in electronic format only.

The Agency reserves the right to request at a later stage that the tenderer provide the documentation in relation to the selection criteria (technical and professional capacity) from any subcontractors.

15. Award criteria

For the evaluation of the quality of service tenderers must provide proof as indicated below and submit the completed and originally signed questionnaire (see Annex I) and costing sheet (see Annex II).

The quality of tenders fulfilling the requirements, as described in Section 3, will be evaluated based on the following criteria. The minimum score indicated must be achieved in each of the criteria A, B and C. Any tender not reaching this minimum score in any criteria shall be eliminated and not evaluated for price.

15.1. *Criteria A – Communication, customer relation and coverage*

A maximum of 20 points can be achieved; a minimum score of 10 is required

- 5 points for communication, customer relations and technical support
 - Please describe which customer services (incl. opening hours), communication methods and frequency will be offered to the Agency.
- 5 points for training for the online system
 - Initial training should be provided regarding the use of online systems, without charging any additional cost. The contractor may propose a remote training.
- 5 points for subject relevance and breadth
 - Please describe the degree to which proposed services for this tender respond to the tender specifications, ability to supply requested titles, arrangements for supply from publishers and draft SLA.
- 5 points for delivery of not-in-the-collection documents
 - Please describe if and how the Agency can order documents that are not in the collections of the Contractor and if an in-depth search system can be offered.

15.2. Criteria B – Accessibility, performance and user friendliness

For the evaluation of accessibility, performance and user friendliness (incl. search facilities, technical requirements, technical performance, user accounts and languages covered), tenderers must provide a free 4-week trial.

A maximum of 20 points can be achieved; a minimum score of 10 is required.

- 5 points for online ordering and system performance
 - An order management system should be offered. The system should allow orders to be placed online and management of the orders as: orders status display, possibility to cancel orders or to renew loans, view history of orders, etc.
 - Confirmation of orders and documents delivery should be sent by email even if the online ordering system is updated accordingly.
- 5 points for integration of the ordering system with other systems
 - Integration with other in-house systems to facilitate ordering would be welcomed.
- 5 points for performance, accessibility and intuitiveness
 - Simple search
 - Boolean search
 - Price indication at point of pre-ordering
- 5 points for available formats and download functionality
 - Electronic delivery (i.e. Pdf) is preferred over paper
 - Immediate download is preferred over delayed delivery

15.3. Criteria C – Delivery, copyright policy and Terms & Conditions

A maximum of 20 points can be achieved; a minimum score of 10 is required.

- 5 points for basic delivery requirements
 - Electronic documents should be delivered through a cloud solution, on the publisher's website or available for download on the Agency's computers, preferably in Pdf format, and in original colour.
- 5 points for speed of delivery
(the faster the delivery the more points can be scored)
 - Standard delivery for an electronic document order should be made within 48-96 hours.
 - Urgent delivery for an electronic document order should be made within 2-24 hours.
- 5 points for copyright for internal dissemination
 - Open access is preferred over copyright fee-based access
 - Compliance with copyright laws

- The Agency would prefer a solution where the electronic documents purchased are available in a cloud based solution to all internal staff.
- 5 points for terms and conditions
 - Please submit a copy of the terms and conditions including subscription license foreseen as response to this call for tender.

15.4. Criteria D – Pricing

Those tenders scoring the minimum score in award criteria A, B and C shall pass to price evaluation.

The award criteria for price shall be evaluated according to the following formula:

$$\frac{\text{Lowest price x weighting for price (40)}}{\text{Tenderer's price}}$$

For the purpose of this evaluation, the price will be calculated on the basis of a scenario of titles provided by the tenderer in Annex II.

“Price” in the above formula shall be constituted by the grand total of costing sheet II-A and II-B.

The scenario in costing sheet II-A is indicative only for the purpose of evaluation and is not binding on the Agency as a future purchase. Tenderers must complete all parts of the costing sheet. Failure to provide a price for any of the 10 titles listed in costing sheet II-A shall result in the tenderer being eliminated and not evaluated for price. Tenderers should not give ranges of prices; if they do so the highest price shall be taken for evaluation purposes.

In addition, tenderers are also requested to provide on a CD-ROM a complete price list of titles offered. This price list shall not be evaluated as part of the award criteria but shall constitute the prices to be charged by the successful tenderer after contract signature.

16. Tender to be submitted

In order to assess each tenderer according to the above-mentioned criteria, the following information must be submitted by the tenderer:

- A letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
- An information sheet on the tenderer indicating:
 - the name and registered business address including telephone number, e-mail address and website address;
 - any other different current or previous trading name in the past three years;
 - the name and contact details of the person whom may be contacted with any queries regarding this tender;
 - the legal status of the tenderer;
 - if the tenderer is a company the company registration number, VAT registration number and date of incorporation;

- if the tenderer is a member of a group of companies and if so the relationship between the tenderer and the ultimate holding company, the name and address of the holding company and its registration number, whether the ultimate holding company would be prepared to guarantee the liabilities in connection with this contract;
- name of the persons authorised to sign contracts on behalf of the tenderer.
- Completed declaration in Annex III relating to Exclusion Criteria.
- Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above).
- Documentation requested to enable assessment of Award Criteria (point 15 above and Annex I).
- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
- Confirmation of acceptance of the draft contract and terms and conditions of tender.
- An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
- Documents as requested in relation to proposed subcontracting.
- Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
- **To be submitted in separate binders or folders, which must be clearly labelled**, a detailed financial tender using the costing sheet attached in Annex II, and exclusive of VAT, signed by an authorised representative of the tenderer.
- **A complete price list of titles offered.**
- Tenderers are requested to make use of the checklist given in Annex IV to ensure that no enclosure has been omitted in their tender.

Annexes

Annex I	Questionnaire
Annex II	Costing Sheet to be used by Tenderers
Annex III	Exclusion Criteria Statement and detail of supporting documentation required
Annex IV	Summary Checklist of Documents which Tenderers must submit
Annex V	Draft Contract

Annex I – Tenderer's Questionnaire

Question / Request	Tenderers Response
Name the document delivery tool that is subject of your response to tender EMA/2013/06/PD.	
CRITERIA A	
Communication, customer relations and technical support: Please describe your services as regards communication and customer relations offered.	
Training: Do you provide training regarding the use of the online system? If yes, please describe your training facilities that will be available to the Agency. If available, please provide links to sample documents, e.g. manuals or video guides.	
Subject relevance and breadth: Please describe the degree to which proposed services for this tender respond to the tender specifications, ability to supply requested titles, arrangements for supply from publishers and draft SLA.	
Delivery of not-in-the-collection documents: Do you provide a service for search and delivery of not-in-the-collection documents? If yes, please describe.	
CRITERIA B	
Online ordering and system performance: Please describe in detail your online ordering and management system? If the system has a separate fee you will be asked to make a price offer in Annex II.	
Please provide credentials for the trial access.	Username: _____ Password: _____

Question / Request	Tenderers Response
Integration of the ordering system: Is your ordering system capable of integration with any other Agency in-house systems?	
Performance, accessibility and intuitiveness: Please describe the search facilities of your ordering system. Will the price be indicated at point of pre-ordering?	
Available formats and download functionality: Will documents be delivered electronically in Pdf format? Is immediate download available?	
CRITERIA C	
Basic delivery requirements: Are you able to provide the basic service regarding the delivery of documents? Please detail the delivery methods that you offer.	
Speed of delivery: Please describe the services offered in this tender.	
Copyright for internal dissemination: Are you able to offer the Agency open access? Are you able to offer the Agency the copyright of documents for internal dissemination? If yes, please describe the conditions. Please describe all copyright conditions you can offer.	
Terms & Conditions: Please attach copy of your terms and conditions or provide link to online version	Attached: ☐ Link: http:// _____

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex II - Costing Sheet

Tenderers must use the following table to submit their tender. **Tenderers should submit this sheet in separate binders or folders which must be clearly labelled, and on a CD-ROM.**

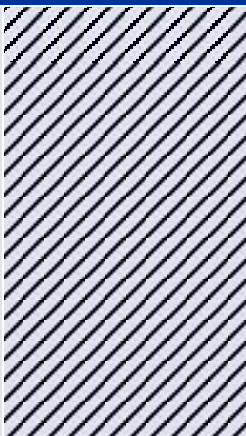
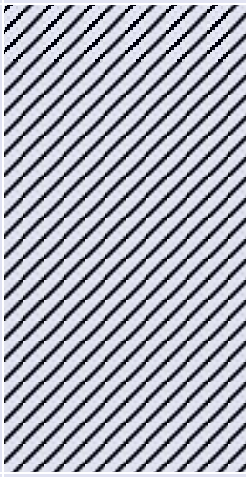
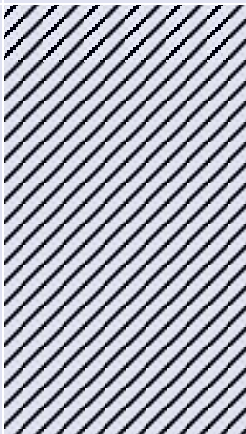
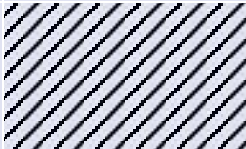
Prices can be submitted in EURO or GBP. Prices submitted in GBP will be converted to EURO according to the European Central Bank exchange rate in force on the date of the deadline of submission of this tender.

Failure to provide a price for any of the 10 titles listed below shall result in the tenderer being eliminated and not evaluated for price. Tenderers should not give ranges of prices; if they do so the highest price shall be taken for evaluation purposes.

Document Supplier's cost must include all copyright and delivery costs. The grand total (II-A + II-B) will constitute price for the purposes of evaluation in the price formula.

Name of tenderer: _____

II-A	Journal title	Document Supplier's cost (€ / £)
1	Journal Title: SEMINARS IN THROMBOSIS AND HEMOSTASIS Publication Year: 2013 Volume: 39 Issue: 2 Pages: 127-140 Author(s): Tagalakis et al. Title of article: Comprehensive Update on the Prevention and Treatment of Venous Thromboembolism in Cancer Patients.	
	Service: Electronic – Urgent delivery (2-24 hours)	
2	Journal Title: MEDICAL CLINICS OF NORTH AMERICA Publication Year: 2012 Volume: 96 Issue: 3 Pages: 621-634 Author(s): Gupta, S. et al Title of article: Immunotherapies in Diabetes Mellitus Type 1.	
	Service: Electronic – Urgent delivery (2-24 hours)	

II-A	Journal title	Document Supplier's cost (€ / £)
3	Journal Title: CLINICAL ENDOCRINOLOGY Publication Year: 2003 Volume: 59 Issue: 6 Pages: 788-92 Author(s): Carvalho LR et al Title of article: Acromegalic features in growth hormone (GH)-deficient patients after long-term GH therapy.	
	Service: Electronic – Urgent delivery (2-24 hours)	
4	Journal Title: ANNALS OF THE NEW YORK ACADEMY OF SCIENCES Publication Year: 2008 Volume: 1141 Issue: - Pages: 284-303 Author(s): Wright, C. Schnoll, S. Bernstein, D. Uhl, G.R. Title of article: Risk evaluation and mitigation strategies for drugs with abuse liability: public interest, special interest, conflicts of interest, and the industry perspective.	
	Service: Electronic – Urgent delivery (2-24 hours)	
5	Journal Title: BIOMETRICS Publication Year: 2005 Volume: 61 Issue: 2 Pages: 355-361 Author(s): Miller, F. Title of article: Variance Estimation in Clinical Studies with Interim Sample Size Re-estimation.	
	Service: Electronic – Urgent delivery (2-24 hours)	
6	Journal Title: JOURNAL OF CROHN'S & COLITIS Publication Year: 2012	

II-A		Journal title	Document Supplier's cost (€ / £)
	Volume: 6 Issue: 7 Pages: 796-799 Author(s): Marques, I. Lagos, A. Reis, J. Pinto, A. Neves, B. Title of article: Reversible Henoch-Schonlein purpura complicating adalimumab therapy.		
	Service: Electronic – Standard delivery (48-96 hours)		
7	Journal Title: ARCHIVES OF DERMATOLOGY Publication Year: 2011 Volume: 147 Issue: 1 Pages: 95-97 Author(s): Jensen, J.D. Fujita, M. Dellavalle, R.P. Title of article: Validation of Psoriasis Clinical Severity and Outcome Measures: Searching for a Gold Standard.		
	Service: Electronic – Standard delivery (48-96 hours)		
8	Journal Title: CURRENT OPINION IN PAEDIATRICS Publication Year: 2011 Volume: 23 Issue: 3 Pages: 325-331 Author(s): Das, S. Langston, C. Fan, L.L. Title of article: Interstitial lung disease in children.		
	Service: Electronic – Standard delivery (48-96 hours)		
9	Journal Title: Thrombosis and haemostasis : international journal Publication Year: 2012 Volume: 108 Issue: 4 Pages: 798-800		

II-A	Journal title	Document Supplier's cost (€ / £)
	Author(s): Trappe, R. Budde, U. Zimmermann, H. Title of article: Haemorrhage due to proteolysis of FXIII and hyperfibrinolysis under vemurafenib treatment of metastatic melanoma. Service: Electronic – Standard delivery (48-96 hours)	
10	Journal Title: JOINT BONE SPINE Publication Year: 2009 Volume: 76 Issue: 6 Pages: 721-722 Author(s): Bret, J. Hernandez, J. Aquilina, C. Zabraniecki, L. Fournie, B. Title of article: Kaposi's disease in a patient on adalimumab for rheumatoid arthritis. Service: Electronic – Standard delivery (48-96 hours)	
	SUB-TOTAL II-A	

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Name of tenderer: _____

II-B	Services	Document Supplier's cost (€ / £)
1	Standard electronic document delivery (48-96 hours)	
2	Express electronic document delivery (2-24 hours)	
3	Online ordering system	
4	Copyright fees	
5	Volume discounts (if available)	
	SUB-TOTAL II-B	

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Name of tenderer: _____

TOTAL COST	Document Supplier's cost (€ / £)
SUB-TOTAL II-A	
SUB-TOTAL II-B	
GRAND TOTAL	

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Annex III - Exclusion Criteria Declaration upon honour and detail of supporting documentation required

It is MANDATORY to complete all parts highlighted in grey.

The undersigned (insert name of the signatory of this form):

☐ Representing the following legal person: (only if the economic operator is a legal person)

Full official name: _____

Official legal form: _____

Full official address: _____

VAT registration number: _____

OR

☐ In [his][her] own name (only if the economic operator is a natural person)

➤ declares that the above-mentioned legal person¹ is not in one of the following situations:

- a) is bankrupt or being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- b) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;
- c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;
- d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;
- e) has been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the European Union's financial interests;
- f) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the European Union's budget.

➤ declares that the natural persons with power of representation, decision-making or control² over the above-mentioned legal entity are not in the situations referred to in b) and e) above;

¹ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

- declares that the above-mentioned legal person³:
- g) has no conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure;
 - acknowledges that the above-mentioned legal person⁴ may be subject to administrative and financial penalties⁵ if any of the declarations or information provided prove to be false.
 - Confirm that the required supporting documentation, as indicated on the next page, is provided and attached to this signed declaration.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters 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 tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

² This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

³ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁴ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁵ As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

Date: _____ Signature of authorised representative: _____

Print name: _____

Position in company: _____

Representing (name of applicant): _____

Annex IV - Summary Checklist of Documents which Tenderers must submit

1. Letter enclosing the tender on the official letter headed paper of the tenderer and signed by an authorised representative of the tenderer.
2. Tender in one original paper copy with one copy of all documents on CD-ROM, containing the following elements:
 - Information sheet on the tenderer (as detailed in Section 16).
 - Completed declaration in Annex III relating to Exclusion Criteria.
 - Documentation requested to enable assessment of Selection Criteria (Section 13 and 14).
 - Documentation requested to enable assessment of Award Criteria (Section 15 and Annex I).
 - A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information, either knowingly or negligently, in response to this tender could result in the tenderer being excluded from future tenders for contracts with the Agency.
 - Confirmation of acceptance of the draft contract and terms and conditions of tender.
 - An undertaking to inform the Agency promptly following any matter which would alter or add to any of the information given in response to this tender.
 - Documents as requested in relation to proposed subcontracting.
 - Tenders submitted by consortia or by groups of service providers must indicate the role, title and experience of each member or of the group.
 - **To be submitted in separate binders or folders, which must be clearly labelled:**
 - a detailed financial tender using the costing sheet attached in Annex II, and exclusive of VAT, signed by an authorised representative of the tenderer.
 - A complete price list of titles offered.

Annex V - Draft contract

Framework contract for supply of goods & services (short-form) for library

European Medicines Agency (hereinafter referred to as "the Agency"), which is represented for the purposes of the signature of this contract by *[name in full and title]*, of the one part, and

[Name of company] whose registered address is at *[complete]* (hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this contract by *[name in full and title]*, a duly authorised officer of the Contractor of the other part,

Have agreed

1. Definitions

1.1 In these Conditions:

'Confidential Information'

means any information intentionally or unintentionally provided directly or indirectly by either the Agency or the Contractor to the other in oral or documentary form or by way of electronically accessible media or other tangible form or by demonstrations;

'Conditions'

means the framework standard terms and conditions of purchase set out in this document and (unless the context otherwise requires) includes any special terms and conditions agreed in Writing between the Agency and the Contractor;

'Contract'

means the contract for the sale and purchase of the Goods and the supply and acquisition of the Services which is constituted by these Conditions (including all terms and conditions incorporated herein by reference) but which is only implemented by the issuance of a Purchase Order;

'Delivery Address'

means the loading bay of the Agency at 1-7 Westferry Loading Bay, Ontario Way, Canary Wharf, London, E14 4HA;

'Goods'

means the goods (including any instalment of the Goods or any part of them) described in the Purchase Order;

'Intellectual Property Rights'

means any database rights, copyright, trademarks, domain names, designs or patents (whether registered or unregistered) including but not limited to all other intellectual or industrial property rights such as know-how, trade secrets and goodwill;

'Purchase Order'

means the Agency's purchase order issued to the Contractor from time to time to implement the purchase of the Goods and/or Services therefrom;

'Price'

means the price of the Goods and/or the charge for the Services;

'Services'

means the services (if any) described in the Purchase Order;

'Specification'

includes the specification, type and quality of the Goods or Services required in the Agency's invitation to tender and technical specifications of *[complete]* and offered in the Contractor's response thereto of *[date]* and includes any plans, drawings data or other information relating to the Goods or Services; and

'Writing'

includes letter, facsimile transmission and comparable means of communication.

1.2 Any reference in these Conditions to a statute or a provision of a statute shall be construed as a reference to that statute or provision as amended, re-enacted or extended at the relevant time.

1.3 The headings in these Conditions are for convenience only and shall not affect their interpretation.

2. Basis of Purchase

2.1 The Purchase Order constitutes an offer by the Agency to purchase the Goods and/or acquire the Services subject to these Conditions.

2.2 These Conditions shall apply to the Contract incorporating the Contractor's standard master agreement as set out in the annex (the "Master Agreement"), but otherwise to the exclusion of any other terms and conditions and or conditions which might be implied by trade custom, practice or other course of dealing on which any quotation has been given to the Agency or subject to which the Purchase Order is accepted or purported to be accepted by the Contractor.

2.3 In the event of a conflict between these Conditions and the Master Agreement of the Contractor, the latter shall prevail to the exclusion of the conflicting provision in these Conditions.

2.4 The Purchase Order will lapse unless unconditionally accepted by the Contractor in Writing within 7 calendar days of its date, unless otherwise so stated in the Purchase Order.

2.5 No variation to the Purchase Order or these Conditions shall be binding unless said variation is required under clause 2.3 above or is agreed in Writing between the authorised representatives of the Agency and the Contractor.

2.6 The Agency will order titles from the first priority supplier, however in the case where the first priority supplier is unable to meet the request within the time limit indicated in the Purchase Order, the Agency would be entitled to send the order to the second priority supplier and the first supplier would be considered unavailable.

3. Specifications

The quantity, quality and description of the Goods

and/or the Services shall, subject as provided in these Conditions, be as specified in the Purchase Order and/or in any applicable Specification supplied by the Agency to the Contractor or agreed in Writing by the Agency. The Contractor shall supply the Goods and perform the Services to a professional standard which might reasonably be expected of it and in any event with reasonable skill and care. It shall perform the Services and provide the Goods in accordance with technical means, standards and procedures based on best professional practice in the relevant field and, in particular, with the ISO 9000 standards.

- 3.2 Any Specification supplied by the Agency to the Contractor, or specifically produced by the Contractor for the Agency, in connection with the Contract, together with the copyright, design rights or any other Intellectual Property Rights in the Specification, shall be the exclusive property of the Agency. The Contractor shall not disclose to any third party or use any such Specification except to the extent that it is or becomes public knowledge through no fault of the Contractor, or as required for the purpose of the Contract.
- 3.3 The Contractor shall comply with all applicable regulations or other legal requirements concerning the manufacture, packaging, packing and delivery of the Goods and the performance of the Services.
- 3.4 The Contractor shall not unreasonably refuse any request by the Agency to inspect and test the Goods during manufacture, processing or storage at the premises of the Contractor or any third party prior to despatch, and the Contractor shall provide the Agency with all facilities reasonably required for inspection and testing.
- 3.5 If as a result of inspection or testing the Agency is not satisfied that the Goods will comply in all respects with the Contract, and the Agency so informs the Contractor within 7 calendar days of inspection or testing, the Contractor shall take such steps as are necessary to ensure compliance.
- 3.6 The Goods shall be marked in accordance with the Agency's instructions and any applicable regulations or requirements of the carrier, and properly packed and secured so as to reach their destination in an undamaged condition.

4. Price of the Goods and Services

- 4.1 The Price of the Goods and the Services shall be as stated in the Purchase Order and, unless otherwise so stated, shall be:
 - 4.1.1 exclusive of any applicable value added tax; and
 - 4.1.2 inclusive of all charges for packaging, packing, shipping, carriage, insurance and delivery of the Goods to the Delivery Address and any duties, imposts or levies other than value added tax.
- 4.2 No increase in the Price may be made (whether on account of increased material, labour or transport costs, fluctuation in rates of exchange or otherwise) without the prior consent of the Agency in Writing.
- 4.3 The Agency shall be entitled to any discount for prompt payment, bulk purchase or volume of purchase customarily granted by the Contractor, whether or not shown on its own terms and conditions of sale.

5. Terms of Payment

- 5.1 The Contractor shall be entitled to invoice the Agency on or at any time after delivery of the Goods or performance of the Services, as the case may be, and each invoice shall quote the number of the Purchase Order.
- 5.2 Payment of the charges under the contract shall be

made only if the Contractor has fulfilled all its contractual obligations by the date on which the invoice is correctly submitted.

- 5.3 Unless otherwise stated in the Purchase Order, the Agency shall pay the Price of the Goods and the Services no later than 30 days from receipt and verification by the Agency of a proper invoice with a breakdown of the Price or, if later, after acceptance of the Goods or Services in question by the Agency. Within four months of completion of the Services and/or delivery of the Goods the Contractor shall submit an admissible invoice, indicating the Contract reference number and the following Agency reference: PO [complete], for payment.

- 5.4 The Agency shall be entitled to set off against the Price any sums owed to the Agency by the Contractor.

6. Delivery

- 6.1 The Goods shall be delivered to, and the Services shall be performed at, the Delivery Address on the date or within the period stated in the Purchase Order, in either case during the Agency's usual business hours.
- 6.2 Where the date of delivery of the Goods or of performance of the Services is to be specified after the placing of Purchase Order, the Contractor shall give the Agency reasonable notice of the specified date.
- 6.3 The time of delivery of the Goods and of performance of the Services is of the essence of the Contract.
- 6.4 A packing note quoting the number of the Purchase Order must accompany each delivery or consignment of the Goods and must be displayed prominently.
- 6.5 If the Goods are to be delivered, or the Services are to be performed, by instalments, the Contract will be treated as a single contract and not severable.
- 6.6 the Agency shall be entitled to reject any Goods delivered which are not in accordance with the Purchase Order, and shall not be deemed to have accepted any Goods until the Agency has had a reasonable time to inspect them following delivery or, if later, within a reasonable time after any latent defect in the Goods has become apparent.
- 6.7 The Contractor shall supply the Agency in good time with any instructions or other information required to enable the Agency to accept delivery of the Goods and performance of the Services.
- 6.8 The Agency shall not be obliged to return to the Contractor any packaging or packing materials for the Goods, whether or not any Goods are accepted by the Agency.
- 6.9 If the Goods are not delivered or the Services are not performed on the due date then, without prejudice to any other remedy, the Agency shall be entitled to deduct from the Price or (if the Agency has paid the Price) to claim from the Contractor by way of liquidated damage for delay one per cent of the Price for every week's delay, up to a maximum of ten per cent.

7. Risk and Property

- 7.1 Risk of damage to or loss of the Goods shall pass to the Agency upon delivery at the Delivery Address to the Agency in accordance with the Contract.
- 7.2 Title to the Goods shall pass to the Agency upon delivery.

8. Warranties, Liability and Indemnity

- 8.1 The Contractor warrants to the Agency that the Goods:
 - 8.1.1 will be of satisfactory quality (within the

- meaning of the Sale of Goods Act 1979, as amended) and fit for any purpose held out by the Contractor or made known to the Contractor in Writing at the time the Purchase Order is placed;
- 8.1.2 will be free from defects in design, material and workmanship;
 - 8.1.3 will correspond with any relevant Specification or sample; and
 - 8.1.4 will comply with all statutory requirements and regulations relating to the sale of the Goods.
- 8.2 The Contractor warrants to the Agency that the Services will be performed by appropriately qualified and trained personnel, with due care and diligence and to such high standard of quality as it is reasonable for the Agency to expect in all the circumstances.
- 8.3 Without prejudice to any other remedy, if any Goods or Services are not supplied or performed in accordance with the Contract, then the Agency shall be entitled:
- 8.3.1 to require the Contractor to repair the Goods or to supply replacement Goods or Services in accordance with the Contract within 7 days; or
 - 8.3.2 at the Agency's sole option, and whether or not the Agency has previously required the Contractor to repair the Goods or to supply any replacement Goods or Services, to treat the Contract as discharged by the Contractor's breach and require the repayment of any part of the Price which has been paid.
- 8.4 Subject to clause 8.5 below and save for indirect or consequential loss, the Contractor shall indemnify the Agency in full against all claims, liability, damages, costs and expenses (including legal and other professional expenses) awarded against or incurred or paid by the Agency as a result of or in connection with:
- 8.4.1 breach of any warranty given by the Contractor in relation to the Goods or the Services;
 - 8.4.2 any claim that the Goods infringe, or their importation, use or resale, infringes, the patent, copyright, design right, trade mark or other intellectual property rights of any other person, except to the extent that the claim arises from compliance with any Specification supplied by the Agency;
 - 8.4.3 any liability under the Consumer Protection Act 1987 in respect of the Goods;
 - 8.4.4 any act or omission of the Contractor or its employees, agents or sub-contractors in supplying, delivering and installing the Goods; and
 - 8.4.5 any act or omission of any of the Contractor's personnel in connection with the performance of the Services.
- 8.5 The Contractor's liability shall be capped at the amount payable under the Purchase Order whereby the liability was incurred, but shall be unlimited in respect of claims arising from death or personal injury caused by the negligence of the Contractor.
- 8.6 In the event of an action being brought by a third party against the Agency in connection with the performance of this Contract which does not fall within 8.4 above, the Contractor shall assist the Agency. Expenditure incurred by the Contractor to this end may be borne by the Agency at its sole discretion.
- 8.7 Neither the Contractor nor the Agency shall be liable to the other or be deemed to be in breach of the Contract

by reason of any delay in performing, or any failure to perform, any of its obligations in relation to the Goods or the Services, if the delay or failure is beyond that party's reasonable control. Without prejudice to the generality of the foregoing, the following shall be regarded as causes beyond either party's reasonable control: Act of God, explosion, flood, tempest, fire or accident; war or threat of war, sabotage, insurrection, civil disturbance or requisition; acts, restrictions, regulations, bye-laws, prohibitions or measures of any kind on the part of any governmental, parliamentary or local authority; import or export regulations or embargoes; strikes, lock-outs or other industrial actions or trade disputes (whether involving employees or either the Contractor or the Agency or of a third party, except where such strikes, lock-outs or other industrial actions or trade disputes only affects staff of the Contractor); difficulties in obtaining raw materials, labour, fuel, parts or machinery; power failure or breakdown in machinery.

9. Termination

- 9.1 The Agency shall be entitled to cancel the Purchase Order in respect of all or part only of the Goods and/or the Services by giving reasonable notice to the Contractor prior to delivery or performance, in which event the Agency's sole liability shall be to pay to the Contractor an amount equal to the Contractor's net cost incurred up to the date of cancellation. Further, the Agency shall be entitled to cancel at any time by giving notice to the Contractor, in which event the Agency's sole liability shall be to pay the Price for the Goods or Services in respect of which the Agency has exercised its right of cancellation, less the Contractor's net saving of cost arising from cancellation.

10. Notice

Any notice or other communication relating to the Contract shall be made in Writing and shall bear the number of the Purchase Order and shall be sent to the appropriate address set out in the Purchase Order or as each party may notify to the other. Ordinary mail shall be deemed to have been received by the Agency on the date on which it is registered by the department responsible and referred to in the Purchase Order. All email and facsimile communications are deemed received on the working day following transmission. All notices or other communications shall be sent to the respective addresses set out in the Purchase Order.

11. Confidentiality

- 11.1 The Contractor undertakes to treat in the strictest confidence and not make use of or divulge or disclose to any third parties any Confidential Information. The Contractor shall continue to be bound by this undertaking after the termination or expiry of this Contract.
- 11.2 The Contractor shall obtain from each member of their Contractor's staff an undertaking that they will respect the confidentiality of any of the Confidential Information and that they will not divulge or disclose to any third parties or use for their own benefit or that of any third party any Confidential Information not available publicly, even after termination or expiry of this Contract.

12. Intellectual Property Rights

- 12.1 The Contractor represents and warrants that the Intellectual Property Rights arising, or utilised in the performance of this Contract are or shall be original and will not infringe any Intellectual Property Rights owned by any third party (including, but without limitation to, all moral rights).
- 12.2 The Contractor assigns to the Agency, with full title guarantee and free from all third party rights, the Intellectual Property Rights arising or created

hereunder.

- 12.3 The Contractor shall, promptly at the Agency's request, do or procure to be done all such further acts and things and the execution of all such other documents as the Agency may from time to time require for the purpose of securing for the Agency the full benefit of the Services, including all right, title and interest in and to the Intellectual Property Rights and all other rights assigned to the Agency in accordance herewith.

13. Intellectual Property Rights Indemnity

- 13.1 The Contractor shall indemnify and hold the Agency harmless from all claims and all direct, indirect or consequential liabilities (including loss of profits, loss of business, depletion of goodwill and similar losses), costs, proceedings, damages and expenses (including legal and other professional fees and expenses) awarded against, or incurred or paid by, the Agency as a result of or in connection with any alleged or actual infringement, whether or not under English law, of any third party's Intellectual Property Rights or other rights arising out of the use or supply of the Goods or the Services or either party's performance of this Contract.

14. General

- 14.1 The Purchase Order is personal to the Contractor and the Contractor shall not assign or transfer or purport to assign or transfer to any other person any of its rights or sub-contract any of its obligations under the Contract without prior consent in Writing from the Agency.
- 14.2 Notwithstanding any other provision of this Contract, nothing in this Contract confers or purports to confer any right to enforce any of its terms on any person who is not a party to it and the provisions of the Contracts (Rights of Third Parties) Act 1999 shall not apply.
- 14.3 No waiver by the Agency of any breach of the Contract by the Contractor shall be considered as a waiver of any subsequent breach of the same or any other provision.
- 14.4 If any provision of the Contract shall become or shall be declared by any court of competent jurisdiction to be invalid or unenforceable in any way, such invalidity or unenforceability shall in no way impair or affect any other provision all of which shall remain in full force and effect.
- 14.5 The Contract shall be governed by the laws of England and Wales, and the Contractor agrees to submit to the exclusive jurisdiction of the Courts of England and Wales.

15. Duration

- 15.1 This Contract shall be concluded for a period of two years.
- 15.2 It may be renewed one time, for a period of up to 24 months.

16. Price Revision

- 16.1 Prices shall be fixed and not subject to revision for purchase orders placed during the first year of performance of the framework contract.
- 16.2 From the beginning of the second year of performance of the framework contract, prices may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the framework contract became effective. Purchase orders shall be placed on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision. The revision of prices shall be determined by the Master Agreement.

Signatures

For the Contractor,
[Company name/forename/surname/title]
Date:

For the Agency,
[forename/surname/title]
Date: