

Draft Framework service contract

Contract number –EMA/2014/49/AUD

European Medicines Agency (hereinafter referred to as "the Agency"), which is represented for the purposes of the signature of this contract by [complete]

of the one part,

and

[official name in full of company and statutory registration number of company]

whose registered address is at [official address in full]

(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

the **Special Conditions** and the **General Conditions** below and the following Annexes:

Annex I – Tender Specifications (Invitation to Tender No EMA/2014/49/AUD of [complete])

Annex II – Contractor's Tender (No [complete] of [complete])

Annex III – Sample Specific Contract

which form an integral part of this framework contract (hereinafter referred to as "the Contract").

In the event of any conflict herein, the terms set out in the Special Conditions shall take precedence over those in the other parts of the Contract. The terms set out in the General Conditions shall take precedence over those in the Annexes. The terms set out in Specific Contracts (as defined below) shall take precedence over those in the Contract. The terms set out in the Tender Specifications (Annex I) shall take precedence over those in the Tender (Annex II).

For the avoidance of doubt, the Contractor acknowledges and agrees that the terms of the Contract shall apply to the exclusion of the Contractor's standard terms and conditions and or any conditions which might be implied by trade custom, practice or other course of dealing.

Subject to the above, the several instruments forming part of the Contract are to be taken as mutually explanatory. Ambiguities or discrepancies within or between such parts shall be explained or rectified by a written instruction issued by the Agency, subject to the rights of the Contractor under Article I.7 should it dispute any such instruction.

I – Special Conditions

Article I.1 - Subject

- I.1.1.** The subject of the Contract is the provision of internal audit services as described in Annex I (the “Services”).
- I.1.2.** Execution of the Contract imposes no obligation on the Agency to purchase the Services. Only the implementation of the Contract through specific contracts in the form set out as Annex III (“Specific Contract”) is binding for the Agency and authorises implementation of the provision of the Services (“Implementation”).
- I.1.3.** Upon Implementation, the Contractor shall provide the Services in accordance with Annex I.
- I.1.4.** All Specific Contracts giving rise to Implementation of the Contract shall conform to the terms set out herein.
- I.1.5.** The Contract does not confer on the Contractor any exclusive right to provide the Services described in Annex I to the Agency. The Contractor is selected as the [*first, second or third*] contractor of a multiple framework contract.

Article I.2 – Duration and implementation of the Contract

- I.2.1.** The Contract and Specific Contracts shall become effective on the date on which they are signed by the last contracting party (the “Effective Date”).
- I.2.2.** Under no circumstances may Implementation take place before the date on which the Contract and Specific Contracts issued hereunder have become effective.
- I.2.3.** This Contract is concluded for a period of 12 (twelve) months with effect from the Effective Date. This contractual period and all other periods specified in the Contract are calculated in calendar months unless otherwise indicated. The Contract may be renewed up to three times, each time for a period of execution of the Services of 12 (twelve) months, with the express written agreement of the parties before the expiry of the Contract, indicating the date on which execution of the Services shall start. Renewal does not imply any modification or deferment of existing obligations.
- I.2.4.** The Specific Contracts must become effective before this Contract expires by effluxion of time or is terminated. The Contract shall continue to apply to such Specific Contracts after its expiry or termination, but no later than 6 (six) months.
- I.2.5.** Within 10 working days of a request for Services being sent by the Agency, the Contractor shall return a duly justified estimate of the resources to be allocated for the execution thereof. Should the Contractor be unable to meet the request for Services, the Contractor shall explain this to the Agency within the same time period and the Agency shall be entitled to send a request to the next contractor on the list. In the event of failure to meet this deadline, as well as in the case of disagreement on the allocation of resources, the Contractor shall be considered unavailable. Within 5 working days of a Specific Contract being sent by the Agency, the Contractor shall return it, duly signed and dated. In the event of failure to observe this deadline, the Contractor shall be considered unwilling or unable to provide the Services and any exclusivity granted to the Contractor pursuant to Article I.1.5 shall be suspended forthwith.

Article I.3 – Contract price

- I.3.1.** The maximum amount of the Contract shall be EUR 480,000 (four hundred and eighty thousand Euros). However this must in no way be construed as a commitment on the Agency to purchase for the maximum amount.
- I.3.2.** The amounts payable for the Services shall be as listed in Annex II exclusive of VAT covering all the Services provided (the “Charges”).
- I.3.3.** It is agreed that the Charges include all other expenditure that may be incurred by the Contractor in performance of this Contract, including travel, subsistence or any other related expenses.
- I.3.4.** The Charges shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the Contract.

From the beginning of the second year of performance of the Contract, the Charges 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 Contract became effective in accordance with Article I.2.1 above. Specific Contracts shall be concluded on the basis of the Charges in force on the date on which they become effective. Such Charges shall not be subject to revision.

This revision shall be determined by the trend in the European Index of Consumer Prices (EICP) published by the Statistical Office of the European Union in its monthly bulletin under the theme of Economy and Finance: Harmonized Indices of Consumer Prices (European Union index) (<http://epp.eurostat.ec.europa.eu>).

Revision shall be calculated in accordance with the following formula:

$$Ar = Ao * \frac{Ir}{Io}$$

Where

Ar = revised total amount

Ao = total amount in the original tender

Io = index for the month in which the validity of the tender expires

Ir = index for the month corresponding to the date of receipt of the letter requesting revision of prices

Article I.4 – Payment periods and formalities

- I.4.1.** Payment of the Charges under the Contract shall be made only if the Contractor has fulfilled all its contractual and legal obligations by the date on which the invoice is correctly submitted. **I.4.2.** Within four months of completion of the Services the Contractor shall submit an admissible invoice, indicating the Contract reference number and the reference number of the Specific Contract to which it refers and the Agency reference which may be communicated from time to time. Payments shall be made on the basis of the invoice issued by the Contractor and verified by the Agency. Any invoice must give a breakdown of the Charges. Subject to verification by the Agency, payment shall be made no later than 30 days from receipt of the invoice.

- I.4.3.** The payment periods for the Charges will be stipulated in the relevant Specific Contracts. The Agency reserves the right to set off any amount owing to it by the Contractor from any amount payable by it to the Contractor.

Article I.5 – Bank account

Payments shall be made direct to the Contractor's bank account, identified as follows:

Name of bank: [complete]
Address of branch in full: [complete]
Exact designation of account holder: [complete]
Full account number including codes: [complete]
IBAN code: [complete]

Article I.6 – Notice/administrative provisions

Any notice or other communication relating to the Contract shall be made in writing, shall bear the Contract number and shall be sent to the appropriate address or email address set out below (or such other address, fax number or person as the relevant party may notify to the other). Ordinary mail sent by prepaid, first class post or recorded delivery shall be deemed to have been received by the Agency on the date on which it is registered by the department responsible and indicated below. All email and facsimile communications are deemed received on the working date following transmission. All notices or other communications shall be sent to the following addresses or email addresses¹:

The Agency:

Head of Audit
European Medicines Agency
Advisory Function - Audit
30 Churchill Place
Canary Wharf
London E14 5EU
UK

Contractor:

Mr/Mrs/Ms [complete]
[Title]
[Company name]
[Official address in full]

Article I.7– Applicable law and settlement of disputes

- I.7.1.** The Contract shall be governed and construed in accordance with the laws of England and Wales.
- I.7.2.** Failing an amicable settlement, the Courts of England and Wales shall have exclusive jurisdiction in any dispute arising out of or in connection with this Contract relating to the performance or the interpretation of the Contract, including non-contractual disputes and claims.

Article I.8 – Termination by either contracting party

Either party may, of its own volition and without being required to pay compensation, terminate the Contract by serving 3 (three) months' formal prior notice. Should the Agency terminate the Contract, the Contractor shall only be entitled to payment corresponding to the Services which are

¹ Fax number and e-mail accounts may be added. If an e-mail account is given, incoming e-mails should be redirected if the account holder is absent and a clause should be added specifying what is considered to be the reference date of the electronic communication (date of sending, receiving or opening).

the subject of valid Specific Contracts before the date termination is notified to become effective ("Termination Date"). On receipt of such notice from the Agency the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitments in relation to the Agency. It shall draw up any documents required by the Contract and its Annexes for the Services provided up to the Termination Date, within a period not exceeding sixty days from the Termination Date.

II – General Conditions

Article II.1 – Performance of the Contract

- II.1.1.** The Contractor shall perform the Services to a high professional standard and in any event with reasonable skill and care. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on it, notably but not limited to those resulting from employment, tax and social legislation.
- II.1.2.** The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for performance of the Services under the laws and regulations in force at the place where the Services are to be provided.
- II.1.3.** Without prejudice to Article II.3 any reference made to any employee, director or other officer or member of staff of the Contractor ("Contractor's Staff") in the Contract shall relate exclusively to individuals involved in the performance of the Services.
- II.1.4.** The Contractor must ensure that:
- II.1.4.1** all of the Contractor's Staff performing the Contract have the professional qualifications, experience and authorisation required for the performance of the Services assigned to them; and
 - II.1.4.2** all of the Contractor's Staff performing the Contract have read, are familiar with and shall abide by the "Health and Safety Information for Contractors" policy or plan as may be applicable from time to time and which can be obtained from the Agency on written request.
- II.1.5.** The Contractor shall neither hold itself out as representing the Agency nor behave in any way that would give such an impression. The Contractor shall inform third parties that it does not belong to the European public service.
- II.1.6.** The Contractor shall have sole responsibility for the Contractor's Staff who perform the Services assigned to them and agrees that no member of the Contractor's Staff shall transfer to the Agency on termination hereof.
- The Contractor shall make provision for the following employment or service relationships with the Contractor's Staff:
- the Contractor's Staff performing the Services assigned to the Contractor may not accept orders or instructions direct from the Agency in relation to how they provide the Services;
 - the Agency may not under any circumstances be considered to be the employer of the Contractor's Staff and the said staff shall undertake if requested by the Agency and as far as they are able not to invoke in respect of the Agency any right arising from the contractual relationship between the Agency and the Contractor.
- II.1.7.** Notwithstanding the above, the Contractor shall indemnify and hold the Agency harmless against all and any claims, loss, cost or expenses awarded against, suffered, incurred, or

agreed to be paid by the Agency as a consequence of any claim arising from any employee or other member of the Contractor's Staff or any claim, assessment or other levy made by any competent taxation or other governmental agency in connection with the provision of the Services by the Contractor to the Agency and/or the termination thereof (howsoever caused) in relation to, inter alia, any claim against the Agency arising from the Transfer of Undertakings (Protection of Employment) Regulations 2006.

- II.1.8.** In the event of disruption resulting from the action of a member of the Contractor's Staff working on the Agency's premises or in the event of the expertise of a member of the Contractor's Staff failing to correspond to the profile required by the Contract, the Contractor shall replace him without delay. The Agency shall have the right to request the replacement of any such member of the Contractor's Staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of performing the Contract under the same contractual conditions. The Contractor shall be responsible for any delay in the execution of the Services assigned to him resulting from the replacement of the Contractor's Staff in accordance with this Article.
- II.1.9.** Should any unforeseen event, action or omission directly or indirectly hamper execution of the Services, either partially or totally, the Contractor shall immediately and on its own initiative record it and report it to the Agency. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken by the Contractor to ensure full compliance with its obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.

Article II.2 – Liability/indemnity

- II.2.1.** The Agency shall not be liable for any claim, loss, cost or expense sustained by the Contractor in performance of the Contract, including any damage caused by the Contractor to third parties during or as a consequence of performance of the Contract, except in the event of wilful misconduct or gross negligence on the part of the Agency.
- II.2.2.** The Contractor shall be liable for any claim, loss (save in respect of consequential loss), cost (including legal and other professional fees) or expenses sustained by the Agency but caused by the Contractor in the performance of the Contract, including that arising in the event of subcontracting under Article II.13. The Agency shall not be liable for any act or default on the part of the Contractor in performance of the Contract.
- II.2.3.** The Contractor shall indemnify and hold the Agency harmless from all such claims, losses, costs and expenses awarded against, suffered, incurred, or agreed to be paid by the Agency, pursuant to Article II.2.2 above and further provide compensation in the event of any action, claim or proceeding brought against the Agency by a third party which requires the Agency to devote management time thereto.
- II.2.4.** The Contractor's liability shall be capped at twice the amount payable under the Specific Contract (as appropriate) whereby the liability was incurred, but shall be unlimited in respect of claims arising (1) from death or personal injury caused by the negligence of the Contractor, (2) due to fraud or fraudulent misrepresentation of the Contractor, or (3) under Article II.8.5.
- II.2.5.** In the event of any action brought by a third party against the Agency in connection with performance of the Contract which does not fall within Articles II.2.2 and II.2.3 above, the Contractor shall assist the Agency including in the event of any alleged breach of Intellectual Property Rights. Expenditure incurred by the Contractor to this end may be borne by the Agency at its sole discretion.

II.2.6. The Contractor shall take out and maintain for the duration of the Contract insurance with a reputable insurance company against all normal business risks and damage relating to performance of the Contract including but not limited to Employer's Liability Insurance (if applicable) and Public Liability Insurance, both to a minimum cover of £5,000,000.00 or the equivalent in Euros. If required by the relevant applicable legislation, the Contractor shall take out supplementary insurance as reasonably required in accordance with reasonably prudent practices in its industry. A copy of all the relevant insurance contracts shall be sent to the Agency should it so request.

Article II.3 - Conflicts of interest

II.3.1. The Contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflicts of interest could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflicts of interest which could arise during performance of the Contract must be notified to the Agency in writing without delay. In the event of any such conflict, the Contractor shall immediately take all necessary steps to resolve it.

The Agency reserves the right to verify that such measures are reasonable and may require additional measures to be taken, if necessary, within a time limit which it shall set. The Contractor shall ensure that the Contractor's Staff are not placed in a situation which could give rise to conflicts of interest. Without prejudice to Article II.1 the Contractor shall replace, immediately and without compensation from the Agency, any member of the Contractor's Staff exposed to such a situation.

II.3.2. The Contractor shall abstain from entering into any contract likely to compromise its independence.

II.3.3. The Contractor declares:

- that it has not made and will not make any offer or agreement with any third party of any type whatsoever from which an advantage can be derived under the Contract,
- that it 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 third 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 performance of the Contract.

II.3.4. The Contractor shall pass on all the relevant obligations in writing to the Contractor's Staff and to any natural person with the power to represent it or take decisions on its behalf as well as to third parties involved in performance of the Contract including subcontractors. A copy of the instructions given and the undertakings made in this respect shall be sent to the Agency should it so request.

Article II.4 – Guarantees and reports

II.4.1. Not applicable.

II.4.2. Not applicable.

II.4.3. Not applicable.**II.4.4.** If any reports to be submitted by the Contractor are a condition for payment, on receipt the Agency shall have the following time for approval of such reports and for contractual payments:

- a) 30 calendar days for straightforward contracts relating to Services;
- b) 60 calendar days for other contracts;
- c) 90 calendar days for contracts involving technical Services, which are particularly complex to evaluate.

The Agency may either approve the report, with or without comments or reservations, or suspend such time period and request additional information, or reject the report and request a new report. If the Agency does not respond within the above time limits, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations or information enclosed. Any new report requested shall be subject to the above provisions.

Article II.5 – General provisions concerning payments

II.5.1. Payments shall be deemed to have been made on the date on which the Agency's account is debited.

II.5.2. The payment period referred to in Article I.4 may be suspended by the Agency at any time if it informs the Contractor that its invoice is incorrect, either because the amount is not due or because the necessary supporting documents have not been properly produced. In case of doubt on the eligibility of the expenditure indicated in the payment request, the Agency may suspend the time limit for payment for the purpose of further verification, including an on-the-spot check, in order to ascertain, prior to payment, that the expenditure is eligible.

The Agency shall notify the Contractor accordingly by registered letter with acknowledgment of receipt or equivalent. Suspension shall take effect from the date of dispatch of the letter. The remainder of the period referred to in Article I.4 shall begin to run again once the suspension has been lifted.

II.5.3. In the event of late payment the Contractor shall be entitled to interest, provided that the calculated interest exceeds EUR 200. In case interest does not exceed EUR 200, the Contractor may claim interest within two months of receiving the payment. Interest shall be calculated at the rate applied by the European Central Bank to its most recent main refinancing operations ("the reference rate") plus eight percentage points ("the margin"). The reference rate in force on the first day of the month in which the payment is due shall apply. Such interest rate is published in the C series of the Official Journal of the European Union. Interest shall be payable for the period elapsing from the calendar day following expiry of the time limit for payment up to the day of payment. Suspension of payment by the Agency may not be deemed to constitute late payment.

II.5.4. Payments shall be executed in Euro or in Pounds Sterling according to the currency of the Contract as specified in Article I.3.2. The Agency shall use the monthly accounting exchange rate established by the European Commission and published on its website, applicable on the day on which the payment order is issued by the Agency. The costs of the transfer shall be borne by the Agency.

Article II.6 – Recovery

II.6.1. If total payments made exceed the amount actually due under the Contract or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse

the appropriate amount on receipt of the debit note, in the manner and within the time limits set by the Agency.

- II.6.2.** In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.
- II.6.3.** the Agency may, after informing the Contractor, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Contractor also has a claim on the Agency that is certain, of a fixed amount and due. The Agency may also claim against any guarantee, where provided for.

Article II.7 – Data protection

The parties shall, and the Contractor shall procure that all its subcontractors shall, comply at all times with the Regulation (EC) No 45/2001, Data Protection Act 1998, the Data Protection Directive (95/46/EC), the Regulation of Investigatory Powers Act 2000, the Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2000 (SI 2000/2699), the Electronic Communications Data Protection Directive (2002/58/EC), the Privacy and Electronic Communications (EC Directive) Regulations 2003 (SI 2426/2003) and all applicable laws and regulations relating to the processing of personal data and privacy, including where applicable the guidance and codes of practice issued by the Information Commissioner (the "Data Protection Legislation") and shall not perform their obligations under the Contract in such a way as to cause either party to breach any of its obligations under the Data Protection Legislation. The Contractor shall immediately notify the Agency in the event that it becomes aware of any breach of the Data Protection Legislation by it or any of its subcontractors in connection with the Contract.

Article II.8 – Ownership of Intellectual Property Rights

- II.8.1.** Any database rights, copyright, trademarks, trade names, domain names, designs or patents (whether registered or unregistered or capable of registration) including but not limited to, all other intellectual or industrial property rights such as know-how, trade secrets and goodwill (the "Intellectual Property Rights"), created by the Contractor, specifically for the Agency, or arising out of the performance of this Contract, shall be owned solely by the Agency, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation. Any intermediary sub-result, raw data, intermediary analysis made available by the Contractor cannot be used by the Agency without the written consent of the Contractor, unless the Contract or Specific Contract explicitly provides for it to be treated as a self-contained result.
- II.8.2.** Where Intellectual Property Rights existed prior to the Contract being entered into and are utilised in the provision of the Services in an incidental way, and which are necessary for the ongoing benefit of those Services, the Contractor shall, or shall procure that any third party owner of said Intellectual Property Rights shall, grant to the Agency a perpetual, royalty free licence (which may be sub-licensed by the Agency) to use and enjoy such pre-existing Intellectual Property Rights.
- II.8.3.** The Contractor shall execute any documents and do all things necessary to vest the Intellectual Property Rights, referred to in Article II.8.1 above, in the ownership of the Agency with full title guarantee and free from all third party rights as may be requested by the Agency from time to time and hereby assigns to the Agency, by way of present amendment of future rights, all such Intellectual Property Rights that may come into existence in the future.

- II.8.4.** The Contractor represents and warrants that the Intellectual Property Rights arising, or utilised, in accordance with Articles II.8.1-2 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).
- II.8.5.** The Contractor shall indemnify and hold the Agency harmless from all claims and liabilities, costs, proceedings, damages and expenses (including legal and other professional fees and expenses) awarded against, suffered, incurred, or agreed to be 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 Services or either party's performance of this Article II.8. The Contractor's liability under this indemnity shall not be subject to the exclusions and limitations of liability set out in Article II.2.4.
- II.8.6.** When the Contractor retains pre-existing rights on parts of the intended outcome of the performance of the Contract which is delivered and finally accepted by the Agency ("the result"), reference shall be inserted to that effect when the result is used as set out in Article II.8.1 with the following disclaimer: © - year – EMA. All rights reserved. Certain parts are licensed under conditions to EMA.

Article II.9 – Confidentiality

- II.9.1.** In this Article, "Information" shall include 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 and whether created or arising in connection with the Services or existing before, on or after the date of the Contract.
- II.9.2.** In this Article, "Confidential Information" shall mean:
- (a) in respect of Information provided in documentary or by way of a presentation or in other tangible form, Information which at the time of provision is marked or otherwise designated to show expressly or is created or arises as a consequence of the provision of the Services or by necessary implication that it is imparted in confidence; and
 - (b) in respect of Information that is imparted orally, any information that the Agency or its representatives informed at the time of disclosure was imparted in confidence; and
 - (c) in respect of Confidential Information imparted orally, any note or record of the disclosure; and
 - (d) any copy of any of the foregoing; and
 - (e) the fact that Services are being provided hereunder.
- II.9.3.** 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 without the prior written consent of the Agency. The Contractor shall continue to be bound by this undertaking after the termination or expiry of this Contract.
- II.9.4.** The Contractor shall obtain from each member of the Contractor's Staff, any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the performance of the Contract, 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.

Article II.10 - Use, distribution and publication of information

- II.10.1.** The Contractor shall authorise the Agency to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, the identity of the Contractor, the subject matter, the duration, the amount paid and any other information required by it to be so published other than that which might reasonably amount to the trade secrets of the Contractor.
- II.10.2.** Unless otherwise provided by the Special Conditions, the Agency shall not be required to distribute or publish the Confidential Information supplied by the Contractor in performance of the Contract. If it decides not to publish the documents or information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from the Agency.
- II.10.3.** Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from the Agency and shall mention the amount paid by the Agency. It shall state that the opinions expressed are those of the Contractor only and do not represent the Agency's official position.
- II.10.4.** The use of Confidential Information obtained by the Contractor in the course of the Contract for purposes other than its performance shall be forbidden, unless the Agency has specifically given prior written authorisation to the contrary.

Article II. 11 – Taxation

- II.11.1.** The Contractor shall have sole responsibility for compliance with the tax laws which apply to it. Failure to comply shall render the relevant invoices invalid.
- II.11.2.** The Contractor recognises that 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.
- II.11.3.** The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and Services required for performance of the Contract are exempt from taxes and duties, including VAT (if applicable).
- II.11.4.** Invoices presented by the Contractor shall indicate its place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

Article II.12 – Force majeure

- II.12.1.** Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties including acts of terrorism which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.
- II.12.2.** Without prejudice to the provisions of Article II.1.9, if either party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgment of receipt or equivalent, stating the nature, likely duration and foreseeable effects.

II.12.3. Neither party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure. Where the Contractor is unable to perform its contractual obligations owing to force majeure, it shall have the right to remuneration only for Services actually executed.

II.12.4. The contracting parties shall take all necessary measures to reduce damage to a minimum including the right of the Agency to terminate and retain new suppliers.

Article II.13 – Subcontracting

II.13.1. The Contractor shall not subcontract the performance of the Services without prior written consent from the Agency nor cause the Contract to be performed in fact by third parties. In the event that the Agency authorises the Contractor to subcontract to a third party the Contractor shall, if requested by the Agency, provide the Agency with a copy of all terms and conditions relating thereto prior to its entry into the same.

II.13.2. Even where the Agency authorises the Contractor to subcontract to third parties, the Contractor shall remain bound by its obligations to the Agency under the Contract and shall guarantee the provision of the Services and be liable for the proper performance of the Contract as if it were performing the Services itself.

II.13.3. The Contractor shall ensure that the subcontracting of its obligations does not affect rights and guarantees to which the Agency is entitled by virtue of the Contract and agrees to indemnify the Agency against any claim, loss, cost and expenses awarded against, suffered, incurred, or agreed to be paid by the Agency as a consequence thereof.

Article II.14 – Assignment

II.14.1. The Contractor shall not assign the rights and obligations arising from the Contract, in whole or in part, without prior written consent from the Agency.

II.14.2. In the absence of the authorisation referred to in II.14.1 above, or in the event of failure to observe the terms thereof, assignment by the Contractor shall be void against and shall have no effect on the Agency.

Article II.15 – Termination by the Agency

II.15.1. Notwithstanding any other term of this Contract, the Agency may terminate the Contract forthwith in the following circumstances:

(a) where the Contractor is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986, has a resolution passed for its winding-up, official management or liquidation (other than pursuant to a consolidation, amalgamation or merger), is dissolved (other than pursuant to a bona fide consolidation, amalgamation or merger), is having its affairs administered by the courts, seeks or becomes subject to the appointment of an administrator, provisional liquidator, conservator, receiver, trustee, custodian or other similar official for it or for all or substantially all its assets, has entered into an arrangement, assignment or composition with or for the benefit of its creditors, has suspended business activities, is the subject of proceedings concerning those matters, a secured party takes possession of all or substantially all of the Contractor's assets or the Contractor has a distress, execution, attachment, sequestration or other legal process levied, enforced or sued on or against all or substantially all of its assets and such secured party maintains possession, or any such process is not dismissed, discharged, stayed or restrained, in each case with thirty (30) days thereafter or is in any analogous

situation arising from a similar procedure provided for in national legislation or regulations applicable to the Contractor;

(b) where the Contractor is an individual, he has been convicted of a criminal offence by a judgement which has the force of *res judicata* (other than minor road traffic offences which do not affect the provision of the Services);

(c) where the Contractor has been sanctioned for professional misconduct proven by any means which the sanctioning authority can reasonably justify;

(d) where the Agency has evidence or seriously suspects the Contractor or any related entity or person of fraud, corruption, commission of any offence under the Bribery Act 2010, involvement in a criminal organisation or any other illegal activity detrimental to the Agency's financial and/or reputational interests;

(e) where the Agency has evidence or seriously suspects the Contractor or any related entity or person, of substantial errors, irregularities or fraud in the award procedure or the performance of the Contract;

(f) where the Contractor was guilty of misrepresentation in supplying the information in the Contractor's Tender or required by the Agency as a condition of entering into the Contract or failed to supply this information;

(g) where there is a change of control of the Contractor and or any holding company of the Contractor whereby the Agency (acting reasonably at all times) considers there is a material detriment to its financial situation or its ability to carry out its functions in the way expected of it. In this clause (g), control means the ability to direct the affairs of another, whether by way of contract, ownership of shares or otherwise howsoever;

(h) where the Contractor has not fulfilled obligations relating to the payment of social security contributions or the payment of taxes, whether or not in connection with the Contractor's Staff, in accordance with the legal provisions of the country in which it is established or with those of the country applicable to the Contract or those of the country where the Contract is to be performed;

(i) where the Contractor is in breach of any obligations under Articles II.3 and II.9.

II.15.2. Notwithstanding any other term of this Contract, the Agency may terminate the contract forthwith in the following circumstances:

(a) where a change in the Contractor's legal, financial, technical or organisational situation could, in the Agency's reasonable opinion, have a significant effect on the performance of the Contract;

(b) where provision of the Services has not actually commenced within one month of the date agreed, and the new date proposed, if any, is considered unacceptable by the Agency;

(c) where the Contractor is unable, through its own fault, to obtain any permit or licence required for performance of the Contract;

(d) where the Contractor is in breach of any other obligations hereunder;

PROVIDED the Contractor fails to remedy said breach, only after receiving formal notice in writing to remedy said breach which specifies the nature of the alleged breach and gives the Contractor the opportunity to remedy the breach within a reasonable period following receipt of the formal notice but in any event not exceeding 14 days.

II.15.3. In case of force majeure, notified in accordance with Article II.12, either contracting party may terminate the Contract at any time, where performance thereof cannot be ensured for a period corresponding to at least one fifth of the period laid down in Article I.2.3 immediately following the event amounting to force majeure occurring.

II.15.4. Prior to termination under point a), b), c) or d) of Article II.15.2, the Contractor shall be given the opportunity to submit its observations.

II.15.5. Termination shall take effect on the date on which a notice with pro-forma acknowledgment of receipt attached terminating the Contract is received by the Contractor, or on any other date indicated in the notice.

II.15.6. Consequences of termination:

In the event of the Agency terminating the Contract in accordance with this Article and without prejudice to any other measures provided for in the Contract, the Contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the letter terminating the Contract, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitments. The Contractor shall draw up any documents required by the Special Conditions for the Services already performed up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

The Agency may claim compensation for any damage suffered and recover any sums paid to the Contractor under the Contract.

On termination the Agency may engage any other contractor to provide the Services. The Agency shall be entitled to claim from the Contractor all extra costs incurred in making good and completing the Services, without prejudice to any other rights or guarantees it has under the Contract.

Article II.15a – Substantial errors, irregularities and fraud attributable to the Contractor

Where, after the award of the Contract, the award procedure or the performance of the Contract prove to have been subject to substantial errors, irregularities or fraud, and where such errors, irregularities or fraud are attributable to the Contractor, the Agency may suspend the Contract, refuse to make payments, may recover amounts already paid or may terminate all contracts concluded with the Contractor, in proportion to the seriousness of the errors, irregularities or fraud.

Article II.16 – Liquidated damages

Should the Contractor fail to perform its obligations under the Contract within the time limits set by the Contract, then, without prejudice to the Contractor's actual or potential liability incurred in relation to the Contract or to the Agency's right to terminate the Contract, the Agency may decide to impose liquidated damages for each and every calendar day of delay according to the following formula:

$$0.3 \times (V/d)$$

V is the price of the relevant Specific Contract.

d is the duration in calendar days specified in the relevant Specific Contract.

The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on its part or of written withdrawal by the Agency within thirty days of the receipt of such arguments, the

decision imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. The Agency and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

Article II.17 – Access, inspection and audits

II.17.1. The Agency and the European Anti-Fraud Office may check or have an audit on the performance of the Contract. It may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf.

Such checks and audits may be initiated during the performance of the Contract and during a period of five years which starts running from the date of expiry of the Contract.

The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the Agency. Audits shall be carried out on a confidential basis.

II.17.2. The Contractor shall, or shall procure that its subcontractors shall gather, compile, correlate, collect and otherwise maintain all relevant accounts, records, books and other information in original documentary form or on easily accessible electronic media, arising in connection with the performance of the Contract for a period of five years which starts running from the date of expiry of the Contract.

II.17.3. The Contractor shall allow the Agency's staff and outside personnel authorised by the Agency the appropriate right of access to sites and premises where the Contract is performed and to all the information, including information in electronic format, needed in order to conduct such checks and audits. The Contractor shall ensure that the information is readily available at the moment of the check or audit and, if so requested, that information be handed over in an appropriate form.

II.17.4. On the basis of the findings made during the audit, a provisional report shall be drawn up. It shall be sent to the Contractor, which shall have 30 days following the date of receipt to submit observations. The final report shall be sent to the Contractor within 60 days following the expiry of that deadline.

On the basis of the final audit findings, the Agency may recover all or part of the payments made and may take any other measures which it considers necessary.

II.17.5. By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EC) No 883/2013 of the European Parliament and the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF), OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by European Union law for the protection of the financial interests of the Agency against fraud and other irregularities. Where appropriate, the findings may lead to recovery by the Agency.

II.17.6. The Court of Auditors shall have the same rights as the Agency, notably right of access, for the purpose of checks and audits.

Article II.18 – Cancellation of Specific Contracts

Where execution of a Specific Contract has not actually commenced within one month of the date foreseen for the commencement of execution and the new date proposed, if any, is considered unacceptable by the Agency, the Agency may cancel such Specific Contract with no prior notice. Cancellation shall take effect from the day after the day on which the Contractor receives a registered letter with acknowledgement of receipt or equivalent.

The Agency may cancel a Specific Contract at any time during execution thereof on the grounds and under the conditions set out in Article II.15 with respect to the part still outstanding. The Contractor shall accept, as the aggregate liability of the Agency, payment of the price of the Services provided by it as at the effective date of cancellation.

Article II.19 – Whole agreement and amendments

This Contract (together with any documents referred to herein and any Specific Contract issued hereunder) constitutes the whole agreement between the parties hereto relating to its subject matter and no variations or amendments to the Contract shall be effective unless the subject of a written agreement concluded by the contracting parties. An oral agreement shall not be binding on the contracting parties.

Article II.20 – Waiver

No forbearance or delay by either party in enforcing its respective rights will prejudice or restrict the rights of that party, and no waiver of any such rights or of any breach of any terms of the Contract will be deemed to be a waiver of any other right or of any later breach. In particular without limitation to the generality of the foregoing, any prior acceptance or approval communicated by the Agency to the Contractor in respect of the Services, or any omission on the part of the Contractor to communicate such prior acceptance or approval shall not relieve the Contractor of its obligations to deliver the Services in accordance with the provisions of the Contract.

Article II.21 - Relationship of the parties

Nothing in this Contract is intended to create a partnership or legal relationship of any kind that would impose liability on one party for the act or failure to act of the other party, or to authorise either party to act as agent for the other party. Neither party shall make representations, act in the name of, on behalf of or otherwise bind the other party.

Article II.22 - Severance

If any provision of this Contract is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed without effect to the remainder of the provisions. If a provision of this Contract that is fundamental to the accomplishment of the purpose of this agreement is held to any extent to be invalid, the Agency and the Contractor shall immediately commence good faith negotiations to remedy such invalidity. Neither party shall unreasonably withhold or delay their agreement to any such matters.

Article II.23 – Rights of third parties

Save where expressly provided, 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.

Signatures

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

For the Agency,
[forename/surname/title]

signature: _____

signature: _____

Done at [place], [date]

Done at London, [date]

In duplicate in English.

Annex I

**Tender specifications (invitation to tender no
EMA/2014/49/AD of [complete])**

Annex II

Contractor's tender (no [complete] of [complete])

Annex III

Sample Specific Contract

Specific Contract no. [complete] to Framework Service Contract no. EMA-2014-49-AUD

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

of the one part,

and

[official name in full of company]

whose registered address is at [official address in full]

(hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this specific contract by [name in full and title], a duly authorised officer of the Contractor

of the other part,

Have agreed

the following Specific Contract and the following Annexes:

Annex I – Request Form for Services

Annex II – Contractor's Response to the Request Form

Annex III - Deliverables

[Other Annexes]

which form an integral part of this specific contract (the "Specific Contract").

This Specific Contract implements the framework contract no. EMA-2014-49-AUD and its Annexes signed by the Agency and the Contractor on [complete date] *[and renewed/amended on complete date]* (the "Framework Contract").

For the avoidance of doubt, the Contractor acknowledges and agrees that the terms of the Specific Contract and Framework Contract shall apply to the exclusion of the Contractor's standard terms and conditions.

Article I.1 - Subject

I.1.1. The subject of this Specific Contract is [short description of subject] (the "Services").

I.1.2. The Contractor undertakes, on the terms set out in the Framework Contract, this Specific Contract and its Annexes, to provide the Services in accordance with the Request Form (Annex I) and the Contractor's Response to the Request Form (Annex II) which shall result in the specified deliverables (Annex III).

Article I.2 - Duration

- I.2.1.** This Specific Contract shall become effective on the date on which it is signed by the last contracting party. Provision of the Services shall start from [date of entry into force of this Specific Contract] [indicate other date] ("Implementation").
- I.2.2.** Implementation of this Specific Contract may under no circumstances begin before the date on which the Specific Contract becomes effective.
- I.2.3.** The duration of the Services shall not exceed [specify duration]. The period allowed for the provision of the Services may be extended only with the express written consent of the Agency before such period elapses.

Article I.3 – Price

The total Charges to be paid by the Agency under the Specific Contract shall be [EUR] exclusive of VAT covering all the Services provided.

Payment shall be made [insert payment terms here].

Invoices must contain the following Agency reference: PO [complete].

Article I.4 – Amendments

No amendment to this Specific Contract shall be effective unless the subject of a written amendment executed by all parties. An oral agreement shall not be binding on either of the parties.

Signatures

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

signature: _____

Done at [place], [date]

For the Agency,
[forename/surname/title]

signature: _____

Done at London, [date]

In duplicate in English.

Annex III
to Specific Contract – to be completed

Deliverables