

Annex IV - Draft concession agreement

Draft Concession Agreement

Training concession – ref. EMA/2014/35/RE

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

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 Concessionaire"), represented for the purposes of the signature of this agreement by [name in full and title], a duly authorised officer of the Concessionaire,

of the other part,

Have agreed

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

Annex I – Technical Specifications (No EMA/2014/35/RE of [complete]) ("Technical Specification")

Annex II – Concessionaire's Proposal (No [complete] of [complete]) ("Concessionaire's Proposal")

which form an integral part of this concession agreement (hereinafter referred to as "the Agreement").

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 Agreement. The terms set out in the General Conditions shall take precedence over those in the Annexes. 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 Concessionaire acknowledges and agrees that the terms of the Agreement shall apply to the exclusion of the Concessionaire'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 Agreement 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 Concessionaire under Article I.7 should it dispute any such instruction.

I – Special Conditions

Article I.1 - Subject

- I.1.1.** The subject of the concession is the delivery of professional, large-scale training and meeting programmes for the European Medicines Agency (the “Services”). The Services means the whole of the services (including without limitation the professional, large-scale training and meeting programmes) or any of them to be provided by the Concessionaire pursuant to this Agreement which are necessary for the Concessionaire to undertake in order to comply with the Technical Specification, the Concessionaire's Proposal and the other provisions of the Agreement.
- I.1.2.** The Concessionaire shall provide the Services assigned to it in accordance with the Technical Specification annexed to the Agreement (Annex I) and in accordance with the provisions of this Agreement.
- I.1.3.** The Agency does not guarantee any minimum number of training courses or information days or number of attendees at training sessions pursuant to this Agreement.
- I.1.4.** This Agreement does not impose any obligation on the Agency or the stakeholders referred to in the Technical Specification to take up any places at training sessions provided by the Concessionaire pursuant to this Agreement.
- I.1.5.** The Concessionaire shall comply with paragraphs 3.1 and 3.8 of the Technical Specification in relation to the location of the training services and shall pay the Agency for use of its premises in accordance with paragraph 3.8 of the Tender Specification.
- I.1.6.** The Concessionaire shall comply with the Technical Specification in relation to the charging and pricing of training courses and information days and shall not make any additional or supplementary charges for such training courses and information days.

Article I.2 - Duration

- I.2.1.** The Agreement shall become effective on the date on which it is signed by the last party. Provision of the Services shall start from date of entry into force of the Agreement (the “Effective Date”).
- I.2.2.** Provision of the Services may under no circumstances begin before the Effective Date.
- I.2.3.** The duration of the Services shall not exceed 48 (forty-eight) months. This period and all other periods specified in the Agreement are calculated in calendar months. The period of provision of the Services may be extended only with the express written agreement of the parties before such period elapses.
- I.2.4.** The Agreement may be renewed up to twice, initially for a period of 24 (twenty-four) months, and consequently by a period of 12 (twelve) months, with the express written agreement of the parties before the Agreement expires, indicating the date on which provision of the Services shall start. Renewal does not imply any modification or deferment of existing obligations.

Article I.3 – Notice / administrative provisions

Any notice or other communication relating to the Agreement shall be made in writing, shall bear the Agreement 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:

The Agency:

European Medicines Agency
Human Medicines Research & Development Support Division
30 Churchill Place
Canary Wharf
London E14 5EU
UK
E-mail: training_concession@ema.europa.eu

Concessionaire:

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

Article I.4– Applicable law and settlement of disputes

- I.4.1.** The Agreement shall be governed and construed in accordance with the laws of England and Wales.
- I.4.2.** 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 Agreement or relating to the performance or the interpretation of the Agreement, including non-agreement disputes and claims.

II – General Conditions

Article II.1 – Performance of the Contract

- II.1.1.** The Concessionaire shall perform the Services to a high professional standard and in any event with reasonable skill and care. The Concessionaire 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 Concessionaire 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 Concessionaire (the “Concessionaire Staff”) in the Agreement shall relate exclusively to individuals involved in the performance of the Services.
- II.1.4.** The Concessionaire must ensure that:
 - II.1.4.1.** all of the Concessionaire Staff performing the Agreement 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 Concessionaire Staff performing the Agreement have read, are familiar with and shall abide by the “Contractor Guidelines and Health and Safety

Information" as may be applicable from time to time and which can be obtained from the Agency on written request.

- II.1.5.** The Concessionaire shall neither hold itself out as representing the Agency nor behave in any way that would give such an impression. The Concessionaire shall inform third parties that it does not belong to the European public service.
- II.1.6.** The Concessionaire shall have sole responsibility for the Concessionaire Staff who execute the Services assigned to them and agrees that no member of the Concessionaire Staff shall transfer to the Agency on termination hereof.

The Concessionaire shall make provision for the following employment or service relationships with the Concessionaire Staff:

- the Concessionaire Staff performing the Services assigned to the Concessionaire 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 Concessionaire 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 Concessionaire.
- II.1.7.** Notwithstanding the above, the Concessionaire 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 Concessionaire 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 Concessionaire 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 Concessionaire Staff working on the Agency's premises or in the event of the expertise of a member of the Concessionaire Staff failing to correspond to the profile required by the Agreement, the Concessionaire shall replace him without delay. The Agency shall have the right to request the replacement of any such member of the Concessionaire Staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of performing the Agreement under the same conditions. The Concessionaire shall be responsible for any delay in the execution of the Services assigned to him resulting from the replacement of the Concessionaire 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 Concessionaire 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 Concessionaire to ensure full compliance with its obligations under the Agreement. In such event the Concessionaire 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 Concessionaire in performance of the Agreement, including any damage caused by the

Concessionaire to third parties during or as a consequence of performance of the Agreement, except in the event of wilful misconduct or gross negligence on the part of the Agency.

- II.2.2.** The Concessionaire 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 Concessionaire in the performance of the Agreement. The Agency shall not be liable for any act or default on the part of the Concessionaire in performance of the Agreement.
- II.2.3.** The Concessionaire 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 total value of the Concession but the Concessionaire's liability shall be unlimited in respect of claims arising (1) from death or personal injury caused by the negligence of the Concessionaire, (2) due to fraud or fraudulent misrepresentation of the Concessionaire, 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 Agreement which does not fall within Articles II.2.2 and II.2.3 above, the Concessionaire shall assist the Agency including in the event of any alleged breach of Intellectual Property Rights. Expenditure incurred by the Concessionaire to this end may be borne by the Agency at its sole discretion.
- II.2.6.** The Concessionaire shall take out and maintain for the duration of the Agreement insurance with a reputable insurance company against all normal business risks and damage relating to performance of the Agreement 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 Concessionaire 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 - Conflict of interests

- II.3.1.** The Concessionaire shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Agreement. 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 Agreement must be notified to the Agency in writing without delay. In the event of any such conflict, the Concessionaire 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 Concessionaire shall ensure that the Concessionaire Staff are not placed in a situation which could give rise to conflicts of interest. Without prejudice to Article II.1 the Concessionaire shall replace, immediately and without compensation from the Agency, any member of the Concessionaire Staff exposed to such a situation.

11.3.2. The Concessionaire shall abstain from entering into any contact likely to compromise its independence.

11.3.3. The Concessionaire 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 Agreement,
- 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 Agreement.

11.3.4. The Concessionaire shall pass on all the relevant obligations in writing to the Concessionaire 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 Agreement. A copy of the instructions given and the undertakings made in this respect shall be sent to the Agency should it so request.

Article 11.4 – Data protection

The parties 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 Concessionaire shall immediately notify the Agency in the event that it becomes aware of any breach of the Data Protection Legislation by it in connection with the Agreement.

Article 11.5 – Ownership of copyrights

11.5.1. 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 Concessionaire, specifically for the Agency, or arising out of the performance of this Agreement, 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 Concessionaire cannot be used by the Agency without the written consent of the Concessionaire, unless the Agreement explicitly provides for it to be treated as a self-contained result.

11.5.2. Where Intellectual Property Rights existed prior to the Agreement 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 Concessionaire 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 to the Agency) to use and enjoy such pre-existing Intellectual Property Rights.

- II.5.3.** The Concessionaire 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.
- II.5.4.** The Concessionaire 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.5.5.** The Concessionaire 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 Concessionaire's liability under this indemnity shall not be subject to the exclusions and limitations of liability set out in Article II.2.4.
- II.5.6.** When the Concessionaire retains pre-existing rights on parts of the intended outcome of the performance of the Agreement 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.6 – Confidentiality

- II.6.1.** In this Article, "Information" shall include any information intentionally or unintentionally provided directly or indirectly by either the Agency or the Concessionaire 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 Agreement.
- II.6.2.** 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.6.3.** The Concessionaire 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 Concessionaire shall continue to be bound by this undertaking after the termination or expiry of this Agreement.

- II.6.4. The Concessionaire shall obtain from each member of the Concessionaire 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 Agreement, 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 Agreement.

Article II.7 - Use, distribution and publication of information

- II.7.1. The Concessionaire shall authorise the Agency to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, the identity of the Concessionaire, the subject matter, the duration, and any other information required by it to be so published, other than that which might reasonably amount to the trade secrets of the Concessionaire.
- II.7.2. Unless otherwise provided by the Special Conditions, the Agency shall not be required to distribute or publish the Confidential Information supplied by the Concessionaire in performance of the Agreement. If it decides not to publish the documents or information supplied, the Concessionaire may not have them distributed or published elsewhere without prior written authorisation from the Agency.
- II.7.3. Any distribution or publication of information relating to the Contract by the Concessionaire 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 Concessionaire only and do not represent the Agency's official position.
- II.7.4. The use of Confidential Information obtained by the Concessionaire in the course of the Agreement for purposes other than its performance shall be forbidden, unless the Agency has specifically given prior written authorisation to the contrary.

Article II.8 – Force majeure

- II.8.1. Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the parties including acts of terrorism which prevents either of them from performing any of their obligations under the Agreement, was not due to error or negligence on their part, 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.8.2. 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.8.3. Neither party shall be held in breach of its obligations if it has been prevented from performing them by force majeure.
- II.8.4. The 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.9 – Assignment

- II.9.1.** The Concessionaire shall not assign the rights and obligations arising from the Agreement, in whole or in part, without prior written consent from the Agency.
- II.9.2.** 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 Concessionaire shall be void against and shall have no effect on the Agency.

Article II.10 – Termination by the Agency

- II.10.1.** Notwithstanding any other term of this Agreement, the Agency may terminate the Agreement forthwith in the following circumstances:

(a) where the Concessionaire 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 Concessionaire's assets or the Concessionaire 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 Concessionaire;

(b) where the Concessionaire 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 Concessionaire 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 Concessionaire 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 Concessionaire or any related entity or person, of substantial errors, irregularities or fraud in the award procedure or the performance of the Agreement;

(f) where the Concessionaire was guilty of misrepresentation in supplying the information in the Concessionaire'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 Concessionaire and or any holding company of the Concessionaire 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 Concessionaire has not fulfilled obligations relating to the payment of social security contributions or the payment of taxes, whether or not in connection with the Concessionaire Staff, in accordance with the legal provisions of the country in which it is established or with those of the country applicable to the Agreement or those of the country where the Agreement is to be performed;

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

II.10.2 Notwithstanding any other term of this Agreement, the Agency may terminate the Agreement forthwith in the following circumstances:

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

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

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

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

PROVIDED the Concessionaire 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 Concessionaire 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.10.3. In case of force majeure, notified in accordance with Article II.12, either party may terminate the Agreement 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.10.4. Prior to termination under point a), b), c), or d) of Article II.15.2, the Concessionaire shall be given the opportunity to submit its observations.

II.10.5. Termination shall take effect on the date on which a notice with pro-forma acknowledgment of receipt attached terminating the Agreement is received by the Concessionaire, or on any other date indicated in the notice.

II.10.6. Consequences of termination:

In the event of the Agency terminating the Agreement in accordance with this Article and without prejudice to any other measures provided for in the Agreement, the Concessionaire shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the letter terminating the Agreement, the Concessionaire shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitments. The Concessionaire 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.

On termination the Agency may engage any other Concessionaire to provide the Services. The Agency shall be entitled to claim from the Concessionaire all extra costs incurred in

making good and completing the Services, without prejudice to any other rights or guarantees it has under the Agreement.

Article II.10a – Substantial errors, irregularities and fraud attributable to the Concessionaire

Where, after the award of the Agreement, the award procedure or the performance of the Agreement prove to have been subject to substantial errors, irregularities or fraud, and where such errors, irregularities or fraud are attributable to the Concessionaire, the Agency may suspend the Agreement.

Article II.11 - Cancellation of Services

Where execution of the Services has not actually commenced within three months 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 Services with no prior notice. Cancellation shall take effect from the day after the day on which the Concessionaire receives a registered letter with acknowledgement of receipt or equivalent.

Article II.12 – Whole agreement and amendments

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

Article II.13 – 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 Agreement 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 Concessionaire in respect of the Services, or any omission on the part of the Concessionaire to communicate such prior acceptance or approval shall not relieve the Concessionaire of its obligations to deliver the Services in accordance with the provisions of the Agreement.

Article II.14 - Relationship of the parties

Nothing in this Agreement 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.15 - Severance

If any provision of this Agreement 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 Agreement that is fundamental to the accomplishment of the purpose of this agreement is held to any extent to be invalid, the Agency and the Concessionaire 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.16 – Rights of third parties

Save where expressly provided, nothing in this Agreement 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 Agreement (Rights of Third Parties) Act 1999 shall not apply.

Signatures

For the Concessionaire,
[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

Technical specifications (no EMA / 2014 / 35 / RE of [complete])

Annex II

Concessionaire's Proposal (no [complete] of [complete])