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Roma, 19/06/2020

Ufficio Attività Negoziale e Gestione del Patrimonio

IQVIA Ltd.
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UK

For the attention: Dr. Michael Fletcher
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PEC: iqviasolutionsitaly@pec.it

SUBJECT: Order for direct assignment of the analysis service on data relating to purchase of medicines in the main European countries for the publication of the National Report on Medicines use in Italy and contribution to a technical board on hospital and *per conto distribution* expenditure aimed at providing evidence for a possible Special Report linked to Covid19 – CIG ZE92D4E55F

ORDER LETTER:

Referring to Your Offer of Ref. No. 2655751, the undersigned Agency, with AIFA Decision No. 215/DG of 19/06/2020, authorizes, pursuant to art. 36, paragraph 2, letter a), Leg. Decree no. 50 of 2016, this order under the conditions set out below and in the Annexes attached hereto.

INTRODUCTION AND ANNEXES:

The introduction and the annexes are an integral part of this Contract Letter.

COMPLIANCE WITH REQUIREMENTS:

With the acceptance of this document, this Company, pursuant to and for the effects of the Presidential Decree no. 445/2000, declares that there exist no causes for exclusion as referred to in art. 80 of the Leg. Decree no. 50 of 2016, for this purpose it is requested that the **Annexes A, A-bis and Mod. 20** forms attached hereto be filled out in all parts and signed.

Pursuant to art. 83 paragraph 9 of the Code, the absence, incompleteness or any other essential irregularity of the aforementioned self-certifications to be made using the above-mentioned **Annexes A, A-bis and Mod. 20**, requires the subject who is the cause thereof, to make payment, to the contracting entity, of the monetary penalty established by this Contract Letter, in the amount equal to one per thousand of the value of the contract. In this case, the contracting entity assigns a term, not greater than ten days, for the addition or regularization of the necessary statements to be made, indicating the content thereof and the persons that must do it. In the event of a non-essential irregularity, or the absence or incompleteness of non-indispensable statements, the contracting entity does not require

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the regularization thereof and does not apply any penalty. In the event that the time period referred to in the second sentence expires without effect, the Company is excluded.

SUBJECT:

The subject of this Contract letter is the analysis service on data relating to purchase of medicines in the main European countries for the publication of the National Report on Medicines use in Italy as well as IQVIA contribution to a technical board on hospital and per conto distribution expenditure aimed at providing evidence for a possible Special Report linked to Covid19, as described in your abovementioned offer. **(Annex C).**

COMPENSATION:

The compensation for the aforementioned service is equal to 27.000,00 euros (twenty-seven thousand/00) excluding VAT as required by law.

EFFECTIVE DATE AND DURATION:

This Contract Letter shall apply from its date of acceptance. The services covered by this Contract Letter shall be rendered as of the stipulation of the abovementioned letter until compliance of the service subject to assignment.

The AIFA may extend the duration, in the circumstances of art. 106, paragraph 11 of Leg. Decree. no. 50/2016.

PROHIBITION OF SUB-CONTRACTING AND ASSIGNMENT OF THIS CONTRACT LETTER:

Sub-contracting of the service which is the subject of this Contract Letter is prohibited, since it was not requested in the offer, and it is in fact also prohibited to assign or to have performed, in whole or in part by another company, the service in question.

PERFORMANCE:

The performance of the service, as described in this Contract Letter and in the document referred to in your above-mentioned Offer, shall be carried out with the constraint of timely and diligent execution.

This Company assumes responsibility for any damages caused to persons, property, equipment, structures and facilities, owing to its fault or the fault of its employees and agrees to indemnify the undersigned Agency for any damage or expense sustained as a result thereof.

This Company relieves the undersigned Agency of any responsibility arising from the non-fulfillment of its own obligations, as employer, with regard to social security, health and safety legislation, mandatory insurance or any other legislation in force.

This Company relieves the undersigned Agency of any responsibility arising from the non-fulfillment on its own part of the obligations regarding the environmental legislation and/or any other legislation in force.

PAYMENT:

The payment shall be made upon presentation of a formal invoice which must necessarily mention the reference CIG ZE92D4E55F to be addressed to: Agenzia Italiana del Farmaco, with main office in Rome, Via del Tritone no. 181 – 00187, C.F. no. 97345810580 – P.I. no. 08703841000.

The payment, subject to compliance with all the contractual conditions and positive feedback from the Agency that the services have been performed according to the

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qualitative and quantitative standards required by the contract, shall be made within 30 days from the date of receipt of the invoice by AIFA.

The invoice shall be sent to the Agency at the following address: salaposta@aifa.gov.it e per cc w.pellegrini@aifa.gov.it, specifying name of the Company, VAT number and date; or Pursuant to art. 25 of the Leg. Decree no. 66/2014, converted with amendments by the Law no. 89/2014, beginning on 03/31/2015, the requirement of electronic invoicing shall have effect; for this purpose we notify that for the Aifa, the **Unique IPA Office Code** is the following: UFE1TR.

Starting from 1 July 2017, pursuant to art. 1, paragraph 1, of the D.L. 50/2017, AIFA is one of the parties for whom the split payment mechanism is envisaged for the splitting of payments. Therefore, the invoices issued from July 1, 2017 must be sent exclusively through the UFE1TR unified code exchange system and with the words VAT "Scission of payments", otherwise the invoices sent with other forms of transmission and with VAT notices other than that "split of payments" will not be considered valid, therefore rejected. The aforementioned accounting spin-off mechanism does not apply to suppliers who issue invoices in:

- Reverse Charge;
- Special VAT regimes, such as for the single-phase publishing scheme, the special scheme for travel agents and the margin scheme;
- The small expenses of the PA are also excluded when the supplier issues a receipt or fiscal receipt.

Starting from 1 July 2017, the self-employed workers who undergo the withholding of income tax withholdings are subject to the obligation to issue invoices to the Public Administration with "split payments".

This payment shall be made by means of bank transfer, with credit to be made on one of the dedicated current accounts, even if not exclusively, to this public commission, addressed to this Company, as expressly indicated in the declaration, issued by the same on the traceability of the cash flows referred to in art. 3 of Law no. 136/2010 in which the persons appointed to conduct transactions on said current bank accounts are listed (**Annex B**).

With the acceptance of this Contract Letter, this Company agrees to inform the undersigned Agency, in a written communication, of any changes in the current account number or of persons authorized to conduct transactions on said account, with therefore the exclusion of any other communication by any other means. Until such communication has been received, the payments made on the aforementioned current account number shall have the effect of discharging the undersigned Agency.

With the signing of this contract, moreover, this Company guarantees assuming and fulfilling all requirements regarding traceability of cash flows cited in law 13 August 2010, no. 136 and subsequent amendments and additions.

Pursuant to art. 3, of the Law 13 August 2010, no. 136 and subsequent amendments and additions, failure to use the dedicated current bank account or of any other instruments suitable for granting full traceability of the transactions related to the payment of the compensation agreed upon and in compliance with the provisions of the above-mentioned law shall constitute cause for termination of this Contract Letter.

CONFIDENTIALITY:

- a. This Company is obligated to maintain the confidentiality of the data and information, including that which passes through the data processing equipment, which it comes to possess and, also, to not knowingly disclose it in any way and in any form and to not make it the subject of use in any capacity for purposes other

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than those strictly necessary for the performance of this Contract Letter, and also for the five years following the termination of effect of the contractual relationship. The obligation cited in the preceding paragraph also exists relative to all the material originating or planned in the performance of this Contract Letter; this obligation does not concern data that are or become part of the public domain.

- b. This Company is responsible for full compliance by its employees, consultants and collaborators, as well as by any subcontractors and their employees, consultants and collaborators, of the aforementioned obligations of secrecy.
- c. In the event of non-compliance with the confidentiality requirements, the undersigned Agency has the right to declare this Contract Letter automatically terminated, it being understood that this Company shall be required to compensate all the damages that may occur to the undersigned Agency.
- d. This Company may cite the essential contents of this Contract Letter, in cases where this is a necessary condition for the participation of this Company in tenders and contracts. Subject to the provisions in the following article "Privacy and requirements for publication on the Contracting Authority's website", this Company agrees, additionally, to comply with the provisions of Leg. Decree no. 196/2003 (Privacy Code).
- e. Without prejudice to the provisions of the following Article "Privacy and publication obligations on the Contracting Authority website", this Company also undertakes to comply with the provisions laid down in the Legislative Decree no. 196/2003 (Privacy Code).

PRIVACY AND REQUIREMENTS FOR PUBLICATION ON THE WEBSITE OF THE CONTRACTING ENTITY:

- a. With the signing of this Contract Letter, the Parties agree to apply the principles of accuracy, lawfulness and transparency to the processing of personal data and in full compliance of the security measures stipulated by Leg. Decree no. 196/03 (Privacy Code), and by the *"Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data"* namely Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 (hereafter, also, the Regulation).
 - The Personal data treated in order to the performance of the Services, connected to the activities covered by the present Letter Contract, as described above in details, shall be strictly limited to the performance of the contractual obligations and to the efficient performance of the services, in compliance with security measures to the above mentioned Regulation and the civil and fiscal rules in force.
 - Within the meaning and for the purposes of mentioned legislation, the contracting Parties shall take note that Data Controller for AIFA, based in Rome via del Tritone n. 181, is the Director General Nicola Magrini.
- b. The Parties state that the personal data provided are accurate and represent the truth, mutually relieving one another of any responsibility for material errors of compilation or for errors arising from the inaccurate attribution of said data in the electronic and hard copy archives.
- c. This Company – pursuant to and for the effects of the provisions of Leg. Decree no. 33 of March 14, 2013, "Reorganization of the rules concerning the obligations of publicity, transparency and dissemination of information by the Public Administration" as well as of art. 32 of the Law 190/2012 "Provisions for the prevention and repression of corruption and illegality of the P.A. [Public Administration]. – expressly consents to the processing and publication on the Internet site of the undersigned Agency of the data related to this tender procedure and to this Contract Letter.

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- d. Your acceptance of this Letter certifies that you have read the methods relating to the processing of personal data, indicated in the information provided pursuant to Art. 13 of the Regulation, which can be found at the following link:

https://www.aifa.gov.it/documents/20142/897150/Informativa_ex_art.13_GDPR.pdf

RIGHT OF WITHDRAWAL AND RESOLUTIVE CONDITION:

It is understood that the undersigned Agency, pursuant to art. 21–e of Law 7 August 1990 no. 241 and subsequent modifications and additions, may at any time withdraw from this Contract Letter, by simply giving prior notice to this Company of at least one month, by written communication, without thereby- in derogation of the provisions of article 1671 c.c.- incurring any additional burden for the undersigned Agency, other than what is owed for the services actually performed up to the date of effect of the withdrawal.

In the case referred in the preceding paragraph, this Company shall exclusively have the right to collect compensation related to the activities conducted up to the time of the termination, withdrawal or lapse or until the expiration date, but not for services provided at a later date; this Company waives, as of now with regard to the undersigned Agency, any claim for indemnification and/or compensation and/or reimbursement for any reason.

Concerning the right of withdrawal from this Contract Letter which may be exercised by the undersigned Agency, art. 1, paragraph 13, of the Decree Law 6 July 2012 no. 95, converted into Law no. 135/2012, is also referenced, where applicable.

This Contract Letter shall also be considered terminated by law in case of occurrence, during the contractual relationship, of the conditions of exclusion from participation in public tenders provided for by Art. 80 of Legislative Decree 50/2016 and by Art. 53 paragraph 16-ter of Legislative Decree 165/2001 with particular reference to the ban on "pantouflage" as well as any other implementing provision of the aforementioned Decree and/or legislative and regulatory framework.

In particular, failure to comply with the "pantouflage" ban pursuant to Art. 53 paragraph 16-ter of Legislative Decree 165/2001, implies that the contracts concluded and the assignments conferred by the Company in violation of the provisions of the aforementioned paragraph 16-ter are null and void, and the Company that concluded or conferred them is prohibited from concluding contracts with AIFA for the following three years with the obligation to return any fees received and verified.

This Company states, finally, that it has read – on the institutional website of the AIFA <https://www.aifa.gov.it/codice-disciplinare-etc>, the item *Activities >Administrative Matters >Disciplinary Code and Code of Conduct* – as provided for by Presidential Decree 16 April 2013, no. 62, Regulation on the Code of Conduct of Public Employees as well as the Supplementary Code of Conduct issued by the AIFA. Pursuant to article 2, paragraph 3 of the Presidential Decree cited, this Company agrees to comply with and to have its employees/agents/suppliers/collaborators, in any capacity, in as far as compatible with the roles and activities performed, comply with the requirements for conduct specified herein, pledging to send a copy of the same to its employees/agents/suppliers, collaborators in an capacity.

The violation of the obligations referred to in the Presidential Decree of 16 April 2013, no. 62 and of all of the preceding, may constitute cause for termination of this Contract Letter at the sole discretion of the AIFA. In particular, the AIFA, having verified the potential violation, shall challenge, in writing, the supplier regarding the fact, assigning a term no greater than ten days for the submission of any counterarguments. When these are not submitted or

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prove to be unacceptable, the AIFA shall terminate this Contract Letter, in any case it is subject to compensation of damages and any actions in a criminal court shall not be affected.

APPLICABLE REGULATIONS AND COMPETENT COURT:

The Parties agree that this Contract Letter is governed by Italian legislation and that for any dispute arising from the interpretation and the performance of this Contract Letter, the Court of Rome shall be competent.

RESPONSIBLE FOR THE PROCEDURE:

Under art. 31, paragraphs 1 and 2 of Leg. Decree. 50/2016 and subsequent amendments, person responsible for the procedure has been nominated Dr. Raffaella Cugini, due to AIFA Decision No. 1766/2018-DG of 10/26/2018.

Head of Department

Digitally signed

Antonino Laganà

Annexes:

A) Declaration referred to art. 80 of the Leg. Decree no. 50/2016 and subsequent modifications and additions, made pursuant to art. 46 and 47 of the Presidential Decree of 28 December 2000, no. 445;

A-bis) Declaration referred to art. 80, paragraph 3 of the Leg. Decree no. 50/2016, made pursuant to art. 46 and 47 of the Presidential Decree of 28 December 2000, no. 445;

Mod. 20) Declaration referred to art. 80, paragraph 1 and 3 of the Leg. Decree no. 50/2016 and subsequent modifications and additions;

B) Traceability of cash flows;

C) Your Offer Ref. No. 2655751.