



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draft Service Contract

Contract number – EMA-2018-30-CO

1. European Medicines Agency hereinafter referred to as 'the contracting authority' represented for the purposes of signing this contract by *[forename, surname, function, department of authorising officer]*

on the one part, and

2. *[Full official name]*

[Official legal form]

[Statutory registration number or ID or passport number]

[Full official address]

[VAT registration number]

[appointed as the leader of the group by the members of the group that submitted the joint tender]

[For joint tenders, repeat these data as many times as there are contractors and continue numbering]

(*[collectively]* 'the contractor'), represented for the purposes of the signature of this contract by *[forename, surname, function of legal representative and name of company in the case of a joint tender]*,

on the other part,

Have agreed

to the **Special Conditions**, the **General Conditions for service contracts** and the following annexes:

Annex I – Tender specifications (reference No EMA-2018-30-CO of *[insert date]*)

Annex II – Contractor's tender (reference No *[complete]* of *[insert date]*)

Annex III - Contractor's terms and conditions of business

which form an integral part of this contract ('the contract').

This contract sets out the obligations of the parties during and after the duration of this contract.

All documents issued by the contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this contract. In all circumstances, in the event of contradiction between this contract and documents issued by the contractor, this contract prevails, regardless of any provision to the contrary in the contractor's documents.

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I. SPECIAL CONDITIONS

I.1. ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this contract, the following rules must be applied:

- (a) The provisions set out in the special conditions take precedence over those in the other parts of the contract.
- (b) The provisions set out in the general conditions take precedence over those in the other annexes.
- (c) The provisions set out in the tender specifications (Annex I) take precedence over those in the tender (Annex II).
- (d) The contractor's terms and conditions (Annex III) shall prevail over the provisions set out in this contract, with the exception of Articles: Article I.3.4 and Article I 3.5 (Entry into force and duration), Article I.5 (Payment Arrangements), Article I.9 and II.9 (Processing of personal data) Article I.12. (Applicable law and settlement of disputes), II.8 (Confidentiality), Article II.19 (Invoices and Value Added Tax) and Article II.24.(Checks and Audits) of this contract which shall apply, regardless of any provision to the contrary in the contractor's terms and conditions.

I.2. SUBJECT MATTER

The subject matter of the contract is subscription to Drug pipeline database(s).

I.3. ENTRY INTO FORCE AND DURATION

I.3.1 The contract enters into force on [complete] if both parties have already signed it.

I.3.2 The *performance of the contract* cannot start before its entry into force.

I.3.3 The duration of the *performance of the contract* must not exceed twelve (12) months. *Performance of the contract* starts from [complete].

I.3.4 The period of performance of the contract may be extended only with the express written agreement of the parties before the expiration of such period.

I.3.5 The contract may be renewed three times, each time for a period of twelve (12) months, with the express written agreement of the parties before the expiry of the Contract, indicating the date on which provision of the Services shall start. Renewal does not change or postpone any existing obligations. For the avoidance of doubt when the last and final renewal period comes to the end, the contract shall be automatically terminated.

I.4. PRICE

I.4.1. Price of the contract and maximum amount

The price payable under this contract including renewals, reimbursement of expenses and price revision is EUR [amount in figures and in words].

I.4.2. Price revision index

Prices are fixed and not subject to revision during the first year of performance of the contract. Thereafter prices may be revised in accordance with the terms and conditions of the contractor.

I.5. PAYMENT ARRANGEMENTS

I.5.1. Payment of the balance

1. The contractor (or leader in the case of a joint tender) may claim the payment of the balance in accordance with Article II.21.6.

The contractor (or leader in the case of a joint tender) must send an invoice in PDF ema.vendorinvoices@ema.europa.eu for payment of the balance due under the contract, as provided for in the tender specifications and accompanied by the following:

a list of all *pre-existing rights* to the *results* or parts of the *results* or a declaration stating that there are no such *pre-existing rights*, as provided for in Article II.13.4;

2. The contracting authority must approve the submitted documents or deliverables and pay within **30** days from receipt of the invoice.

3. The contracting authority may suspend the time limit for payment specified in point (2.) in accordance with Article II.21.7. Once the suspension is lifted, the contracting authority shall give its approval and pay within the remainder of the time-limit indicated in point (2.) unless it rejects partially or fully the submitted documents or deliverables.

[Option: for contractors for which VAT is due in Belgium]

[In Belgium, use of this contract constitutes a request for VAT exemption No 450, Article 42, paragraph 3.3 of the VAT code (circular 2/1978), provided the invoice includes the statement: 'Exonération de la TVA, Article 42, paragraphe 3.3 du code de la TVA (circulaire 2/1978)'.]

[Option: for contractors for which VAT is due in Luxembourg]

[In Luxembourg, the contractor must include the following statement in the invoices: "Commande destinée à l'usage officiel de l'Union européenne. Exonération de la TVA Article 43 § 1 k 2ème tiret de la loi modifiée du 12.02.79. 'In the case of intra-Community purchases, the statement to be included in the invoices is: "For the official use of the European Union. VAT Exemption / European Union/ Article 151 of Council Directive 2006/112/EC.'"]

I.6. GUARANTEES

Guarantees are not applicable to this contract.

I.6.1. Performance guarantee

Performance guarantee is not applicable to this contract.

I.6.2. Retention money guarantee

Retention money guarantee is not applicable to this contract.

I.7. BANK ACCOUNT

Payments must be made to the contractor's (or leader's in the case of a joint tender) bank account denominated in [euro] [*insert local currency where the receiving country does not allow transactions in EUR*], identified as follows:

Name of bank:

Full address of branch:

Exact denomination of account holder:

Full account number including bank codes:

[IBAN¹ code:]

Any change to the contractor's bank account details (including any factoring arrangements entered into by the contractor in respect of sums due under the contract) shall be communicated by letter to the contracting authority by the contract signatory or other duly authorised person; the contracting authority shall issue an acknowledgement.

I.8. COMMUNICATION DETAILS

For the purpose of this contract, communications must be sent to the following addresses:

The Agency:

European Medicines Agency

Communication Department

Orlyplein 24

1043 DP Amsterdam

Email address: *insert functional mailbox*]

Contractor (or leader in the case of a joint tender):

[*Full name*]

[*Function*]

[*Company name*]

[*Full official address*]

E-mail: [*complete*]

I.9. PROCESSING OF PERSONAL DATA

I.9.1 Processing of personal data by the contracting authority

For the purpose of Article II.9.1,

(a) the data controller is: Head of Stakeholders and Communication Division of EMA-;

¹ BIC or SWIFT code for countries with no IBAN code.

(b) the data protection notice is available at:
https://www.ema.europa.eu/documents/other/privacy-statement-processing-personal-data-context-public-procurement-procedures_en.pdf

I.9.2 Processing of personal data by the contractor

This clause is not applicable to this contract.

I.10. EXPLOITATION OF THE RESULTS OF THE CONTRACT

I.10.1. Detailed list of modes of exploitation of the results

In accordance with Article II.13.1 whereby the contracting authority acquires ownership of the *results* as defined in this contract, including the tender specifications, these *results* may be used for any of the following modes of exploitation:

use for its own purposes:

- making available to the staff of the contracting authority;
- making available to the persons and entities working for the contracting authority or cooperating with it, including contractors, subcontractors whether legal or natural persons, Union institutions, agencies and bodies, Member States' institutions;
- installing, uploading, processing;
- arranging, compiling, combining, retrieving;
- copying, reproducing in whole or in part and in unlimited number of copies.

The list above is in addition to whatever rights already accrued to the contracting authority on the basis of existing exceptions in the applicable legislation, such as the copyright exception to ensure the proper performance or reporting of administrative proceedings, in cases where such exceptions apply.

I.10.2. Licence or transfer of pre-existing rights

All *pre-existing rights* incorporated in the *results*, if any, are licensed to the contracting authority as set out in Article II.13.2.

I.10.3. Provision of list of pre-existing rights and documentary evidence

The contractor must provide the contracting authority with a list of *pre-existing rights* as set out in Article II.13.4 together with the invoice for payment of the balance at the latest.

I.11. TERMINATION BY EITHER PARTY

Either party may, terminate the contract by sending *formal notification* to the other party with **three months'** written notice.

If the contract is terminated:

- (a) neither party is entitled to compensation;
- (b) the contractor is entitled to payment only for the services provided before termination takes effect.

The second, third and fourth paragraphs of Article II.18.4 apply.

I.12. APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.12.1. The contract is governed by Union law, complemented, where necessary, by the law of Belgium.

I.12.2. The courts of Brussels have exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the contract.

I.13. –NOT APPLICABLE

SIGNATURES

For the contractor,

For the contracting authority,

[Company name/forename/surname/position]

[forename/surname/position]

Signature: _____

Signature: _____

Done at [place], [date]

Done at [place], [date]

In duplicate in English.

II. GENERAL CONDITIONS FOR THE SERVICE CONTRACT

II.1. DEFINITIONS

For the purpose of this contract, the following definitions (indicated in *italics* in the text) apply:

'Breach of obligations': failure by the contractor to fulfil one or more of its contractual obligations.

'Confidential information or document': any information or document received by either party from the other or accessed by either party in the context of the *performance of the contract*, that any of the parties has identified as confidential. It may not include information that is publicly available;

'Conflict of interest': a situation where the impartial and objective *performance of the contract* by the contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the contracting authority or any third party related to the subject matter of the contract;

'Creator': means any natural person who contributes to the production of the *result*;

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the contract. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be invoked as *force majeure*, unless they stem directly from a relevant case of *force majeure*;

'Formal notification' (or 'formally notify'): form of communication between the parties made in writing by mail or e-mail, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

'Fraud': an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests;

'Grave professional misconduct': a violation of applicable laws or regulations or ethical standards of the profession to which a contractor or a related person belongs, including any conduct leading to sexual or other exploitation or abuse, or any wrongful conduct of the contractor or a related person which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence.

'Irregularity': any infringement of a provision of Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the Union's budget.

'Notification' (or 'notify'): form of communication between the parties made in writing including by electronic means;

'Performance of the contract': the execution of tasks and delivery of the purchased services by the contractor to the contracting authority;

'Personnel': persons employed directly or indirectly or contracted by the contractor to perform the contract;

'Pre-existing material': any material, document, technology or know-how which exists prior to the contractor using it for the production of a *result* in the *performance of the contract*;

'Pre-existing right': any industrial and intellectual property right on *pre-existing material*; it may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the *creator*, the contracting authority as well as to any other third parties;

'Professional conflicting interest': a situation in which the contractor's previous or ongoing professional activities affect its capacity to perform the contract to an appropriate quality standard.

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the contractor, or who has powers of representation, decision or control with regard to the contractor;

'Result': any intended outcome of *the performance of the contract*, whatever its form or nature, which is delivered and finally or partially approved by the contracting authority. A *result* may be further defined in this contract as a deliverable. A *result* may, in addition to materials produced by the contractor or at its request, also include *pre-existing materials*;

II.2. ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

II.3. SEVERABILITY

Each provision of this contract is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the contract. This does not affect the legality, validity or enforceability of any other provisions of the contract, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in accordance with Article II.11. The contract must be interpreted as if it had contained the substitute provision as from its entry into force.

II.4. PERFORMANCE OF THE CONTRACT

II.4.1 The contractor must provide services of high quality standards, in accordance with the state of the art in the industry and the provisions of this contract, in particular the tender specifications and the terms of its tender. Where the contracting authority has the right to make modifications to the *results*, they must be delivered in a format and with the necessary information which effectively allow such modifications to be made in a convenient manner.

II.4.2 The contractor must comply with the minimum requirements provided for in the tender specifications. This includes compliance with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU², compliance with data protection obligations resulting from Regulation (EU) 2016/679³ and Regulation (EU) 2018/1725⁴.

² OJ L 94 of 28.03.2014, p. 65

³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119, 4.5.2016, p. 1, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG

- II.4.3** The contractor must obtain any permit or licence required in the State where the services are to be provided.
- II.4.4** All periods specified in the contract are calculated in calendar days, unless otherwise specified.
- II.4.5** The contractor must not present itself as a representative of the contracting authority and must inform third parties that it is not part of the European public service.
- II.4.6** The contractor is responsible for the *personnel* who carry out the services and exercises its authority over its *personnel* without interference by the contracting authority. The contractor must inform its *personnel* that:
- (a) they may not accept any direct instructions from the contracting authority; and
 - (b) their participation in providing the services does not result in any employment or contractual relationship with the contracting authority.
- II.4.7** The contractor must ensure that the *personnel* performing the contract and any future replacement *personnel* possess the professional qualifications and experience required to provide the services, as the case may be on the basis of the selection criteria set out in the tender specifications.
- II.4.8** At the contracting authority's reasoned request, the contractor must replace any member of *personnel* who:
- (a) does not have the expertise required to provide the services; or
 - (b) has caused disruption at the premises of the contracting authority.
- The contractor bears the cost of replacing its *personnel* and is responsible for any delay in providing the services resulting from the replacement of *personnel*.
- II.4.9** The contractor must record and report to the contracting authority any problem that affects its ability to provide the services. The report must describe the problem, state when it started and what action the contractor is taking to resolve it.
- II.4.10** The contractor must immediately inform the contracting authority of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.5. COMMUNICATION BETWEEN THE PARTIES

II.5.1 Form and means of communication

Any communication of information, notices or documents under the contract must:

- (a) be made in writing in paper or electronic format in the language of the contract;
- (b) bear the contract number;
- (c) be made using the relevant communication details set out in Article I.8; and
- (d) be sent by mail or e-mail

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

⁴ Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39, 21.11.2018, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

The parties agree that any communication made by e-mail has full legal effect and is admissible as evidence in judicial proceedings.

II.5.2 Date of communications by mail and e-mail

Any communication is deemed to have been made when the receiving party receives it, unless this contract refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.8. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by e-mail or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the contracting authority is deemed to have been received by the contracting authority on the date on which the department responsible referred to in Article I.8 registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.6. LIABILITY

- II.6.1** The contracting authority is not liable for any damage or loss caused by the contractor, including any damage or loss to third parties during or as a consequence of *performance of the contract*.
- II.6.2** If required by the relevant applicable legislation, the contractor must take out an insurance policy against risks and damage or loss relating to the *performance of the contract*. It must also take out supplementary insurance as reasonably required by standard practice in the industry. Upon request, the contractor must provide evidence of insurance coverage to the contracting authority.
- II.6.3** The contractor is liable for any loss or damage caused to the contracting authority during or as a consequence of *performance of the contract*, including in the event of subcontracting, but only up to an amount not exceeding three times the total amount of the contract. However, if the damage or loss is caused by the gross negligence or wilful misconduct of the contractor or of its *personnel* or subcontractors, as well as in the case of an action brought against the contracting authority by a third party for breach of its intellectual property rights, the contractor is liable for the whole amount of the damage or loss.
- II.6.4** If a third party brings any action against the contracting authority in connection with the *performance of the contract*, including any action for alleged breach of intellectual property rights, the contractor must assist the contracting authority in the legal proceedings, including by intervening in support of the contracting authority upon request. If the contracting authority's liability towards the third party is established and that such liability is caused by the contractor during or as a consequence of the *performance of the contract*, Article II.6.3 applies.
- II.6.5** If the contractor is composed of two or more economic operators (i.e. who submitted a joint tender), they are all jointly and severally liable to the contracting authority for the *performance of the contract*.
- II.6.6** The contracting authority is not liable for any loss or damage caused to the contractor during or as a consequence of *performance of the contract*, unless the loss or damage was caused by wilful misconduct or gross negligence of the contracting authority.

II.7. CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.7.1 The contractor must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.

II.7.2 The contractor must *notify* the contracting authority in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the *performance of the contract*. The contractor must immediately take action to rectify the situation.

The contracting authority may do any of the following:

- (a) verify that the contractor's action is appropriate;
- (b) require the contractor to take further action within a specified deadline;

II.7.3 The contractor must pass on all the relevant obligations in writing to:

- (a) its *personnel*;
- (b) any natural person with the power to represent it or take decisions on its behalf;
- (c) third parties involved in the *performance of the contract*, including subcontractors.

The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.8. CONFIDENTIALITY

II.8.1 The contracting authority and the contractor must treat with confidentiality any information or documents, in any format, disclosed in writing or orally relating to the *performance of the contract* and identified as confidential.

II.8.2 Each party must:

- (a) not use *confidential information or documents* for any purpose other than to perform its obligations under the contract without the prior written agreement of the other party;
- (b) ensure the protection of such *confidential information or documents* with the same level of protection as its own *confidential information* and in any case with due diligence;
- (c) not disclose, directly or indirectly, *confidential information or documents* to third parties without the prior written agreement of the other party.

II.8.3 The confidentiality obligations set out in this Article are binding on the contracting authority and the contractor during the *performance of the contract* and for as long as the information or documents remain confidential unless:

- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- (b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligation;
- (c) the applicable law requires the disclosure of the *confidential information or documents*.

II.8.4 The contractor must obtain from 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*, a commitment that they will comply with this Article. At the request of the contracting authority, the contractor must provide a document providing evidence of this commitment.

II.8.5 The contractor agrees that any data or information related to the contracting authority's use of the services (either concerning individual users of the service or in aggregate format) is identified as confidential and shall be treated by the contractor in accordance with this Article II.8.

II.9. PROCESSING OF PERSONAL DATA

II.9.1 Processing of personal data by the contracting authority

Any personal data included in or relating to the contract, including its implementation, shall be processed in accordance with Regulation (EU) No 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the contract by the data controller.

The contractor or any other person whose personal data is processed by the data controller in relation to this contract has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) No 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this contract have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

Details concerning the processing of personal data are available in the data protection notice referred to in Article I.9.

II.9.2 Processing of personal data by the contractor

This clause is not applicable to this contract.

II.10. SUBCONTRACTING

II.10.1 The contractor must not subcontract and have the contract performed by third parties beyond the third parties already mentioned in its tender without prior written authorisation from the contracting authority.

II.10.2 Even if the contracting authority authorises subcontracting, the contractor remains bound by its contractual obligations and is solely responsible for the performance of this contract.

II.10.3 The contractor must ensure that the subcontract does not affect the rights of the contracting authority under this contract, particularly those under Articles II.8, II.13 and II.24.

II.10.4 The contracting authority may request the contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.18.1.

II.11. AMENDMENTS

II.11.1 Any amendment to the contract must be made in writing before all contractual obligations have been fulfilled.

II.11.2 Any amendment must not make changes to the contract that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers.

II.12. ASSIGNMENT

- II.12.1** The contractor must not assign the rights and obligations arising from the contract, including claims for payments or factoring, without prior written authorisation from the contracting authority. In such cases, the contractor must provide the contracting authority with the identity of the intended assignee.
- II.12.2** Any right or obligation assigned by the contractor without authorisation is not enforceable against the contracting authority.

II.13. INTELLECTUAL PROPERTY RIGHTS

II.13.1. Ownership of the rights in the results

The contracting authority acquires irrevocably worldwide ownership of the *results* and of all intellectual property rights on the newly created materials produced specifically for the contracting authority under the contract and incorporated in the *results*, without prejudice however to the rules applying to *pre-existing rights on pre-existing materials*, as per Article II.13.2.

The intellectual property rights so acquired include any rights, such as copyright and other intellectual or industrial property rights, to any of the *results* and in all technological solutions and information created or produced by the contractor or by its subcontractor in *performance of the contract*. The contracting authority may exploit and use the acquired rights as stipulated in this *contract*. The contracting authority acquires all the rights as from the moment the contractor has created the *results*.

The payment of the price includes any fees payable to the contractor about the acquisition of ownership of rights by the contracting authority including for all modes of exploitation and of use of the *results*.

II.13.2. Licensing rights on pre-existing materials

Unless provided otherwise in the special conditions, the contracting authority does not acquire ownership of *pre-existing rights* under this contract.

The contractor licenses the *pre-existing rights* on a royalty-free, non-exclusive and irrevocable basis to the contracting authority, which may use the *pre-existing materials* for all the modes of exploitation set out in this contract. Unless otherwise agreed, the licence is non-transferable and cannot be sub-licensed, except as provided hereafter:

(a) the *pre-existing rights* can be sub-licensed by the contracting authority to persons and entities working for it or cooperating with it, including contractors and subcontractors, whether legal or natural persons, but only for the purpose of their mission for the contracting authority;

(b) if the *result* is a "document" such as a report or a study, and it is meant to be published, the existence of *pre-existing materials* in the *result* may not prevent the publication of the document, its translation or its "reuse", it being understood however that the "reuse" may only be made of the *result* as a whole and not of the *pre-existing materials* taken separately from the *result*; for the sake of this provision, "reuse" and "document" have the meaning given by the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU).

All *pre-existing rights* are licensed to the contracting authority from the moment the *results* are delivered and approved by the contracting authority.

The licensing of *pre-existing rights* to the contracting authority under this contract covers all territories worldwide and is valid for the duration of intellectual property rights protection.

The payment of the price as set out in the contract is deemed to also include any fees payable to the contractor in relation to the licensing of *pre-existing rights* to the contracting authority, including for all forms of exploitation and of use of the *results*.

Where *performance of the contract* requires that the contractor uses *pre-existing materials* belonging to the contracting authority, the contracting authority may request that the contractor signs an adequate licence agreement. Such use by the contractor will not entail any transfer of rights to the contractor and is limited to the needs of this contract.

II.13.3. Exclusive rights

The contracting authority acquires the following exclusive rights:

- (a) reproduction: the right to authorise or prohibit direct or indirect, temporary or permanent reproduction of the *results* by any means (mechanical, digital or other) and in any form, in whole or in part;
- (b) communication to the public: the exclusive right to authorise or prohibit any display, performance or communication to the public, by wire or wireless means, including the making available to the public of the *results* in such a way that members of the public may access them from a place and at a time individually chosen by them; this right also includes the communication on the internet and broadcasting by cable or by satellite;
- (c) distribution: the exclusive right to authorise or prohibit any form of distribution of *results* or copies of the *results* to the public, by sale or otherwise;
- (d) rental: the exclusive right to authorise or prohibit rental or lending of the *results* or of copies of the *results*;
- (e) adaptation: the exclusive right to authorise or prohibit any modification of the *results*;
- (f) translation: the exclusive right to authorise or prohibit any translation, adaptation, arrangement, creation of derivative works based on the *results*, and any other alteration of the *results*, subject to the respect of moral rights of authors, where applicable;
- (g) where the *results* are or include a database: the exclusive right to authorise or prohibit the extraction of all or a substantial part of the contents of the database to another medium by any means or in any form; and the exclusive right to authorise or prohibit the re-utilization of all or a substantial part of the contents of the database by the distribution of copies, by renting, by on-line or other forms of transmission;
- (h) where the *results* are or include a patentable subject-matter: the right to register them as a patent and to further exploit such patent to the fullest extent;
- (i) where the *results* are or include logos or subject-matter which could be registered as a trademark: the right to register such logo or subject-matter as a trademark and to further exploit and use it;
- (j) where the *results* are or include know-how: the right to use such know-how as is necessary to make use of the *results* to the full extent provided for by this contract, and the right to make it available to contractors or subcontractors acting on behalf of the contracting authority, subject to their signing of adequate confidentiality undertakings where necessary;
- (k) where the *results* are documents:
 - (i) the right to authorise the reuse of the documents in conformity with the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU), to the extent it is applicable and the documents fall within its scope and are not excluded by any of its provisions; for the sake of this provision, 'reuse' and 'document' have the meaning given to it by this Decision;
 - (ii) the right to store and archive the *results* in line with the document management rules applicable to the contracting authority, including digitisation or converting the format for preservation or new use purposes;
- (l) where the *results* are or incorporate software, including source code, object code and, where relevant, documentation, preparatory materials and manuals, in addition to the other rights mentioned in this Article:
 - (i) end-user rights, for all uses by the contracting authority or by subcontractors which result from this contract and from the intention of the parties;

- (ii) the rights to receive both the source code and the object code;
- (m) the right to license to third parties any of the exclusive rights or of the modes of exploitation set out in this contract; however, for *pre-existing materials* which are only licensed to the contracting authority the right to sub-license does not apply, except in the two cases foreseen by Article II.13.2.;
- (n) to the extent that the contractor may invoke moral rights, the right for the contracting authority, except where otherwise provided in this contract, to publish the *results* with or without mentioning the *creator(s)*' name(s), and the right to decide when and whether the *results* may be disclosed and published.
- (o)

The contractor warrants that the exclusive rights and the modes of exploitation may be exercised by the contracting authority on all parts of the *results*, be it via a transfer of ownership of the rights, on those parts which were specifically created by the contractor, or via a licence of the pre-existing rights, on those parts consisting of *pre-existing materials*. Where *pre-existing materials* are inserted in the *results*, the contracting authority may accept reasonable restrictions impacting on the above list, provided that the said materials are easily identifiable and separable from the rest, that they do not correspond to substantial elements of the *results*, and that, should the need arise, satisfactory replacement solutions exist, at no additional costs to the contracting authority. In such case, the contractor will have to clearly inform the contracting authority before making such choice and the contracting authority has the right to refuse it.

II.13.4. Identification of pre-existing rights

When delivering the *results*, the contractor must warrant that, for any use that the contracting authority may envisage within the limits set in this contract, the *results* and the *pre-existing material* incorporated in the *results* are free of claims from *creators* or from any third parties and all the necessary *pre-existing rights* have been obtained or licensed.

To that effect, the contractor must establish a list of all *pre-existing rights* to the *results* of this contract or parts thereof, including identification of the rights' owners. If there are no *pre-existing rights* to the *results*, the contractor must provide a declaration to that effect. The contractor must provide this list or declaration to the contracting authority together with the invoice for payment of the balance at the latest.

II.13.5. Evidence of granting of pre-existing rights

Upon request by the contracting authority, the contractor must, in addition to the list mentioned under Article II.13.4., provide evidence that it has the ownership or the right to use all the listed *pre-existing rights*, except for the rights owned or licensed by the contracting authority. The contracting authority may request this evidence even after the end of this contract.

This evidence may refer, for example, to rights to: parts of other documents, images, graphs, sounds, music, tables, data, software, technical inventions, know-how, IT development tools, routines, subroutines or other programs ('background technology'), concepts, designs, installations or pieces of art, data, source or background materials or any other parts of external origin.

This evidence must include, as appropriate:

- (a) the name and version number of a software product;
- (b) the full identification of the work and its author, developer, *creator*, translator, data entry person, graphic designer, publisher, editor, photographer, producer;
- (c) a copy of the licence to use the product or of the agreement granting the relevant rights to the contractor or a reference to this licence;
- (d) a copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the *results* were created by its *personnel*;
- (e) the text of the disclaimer notice if any.

Provision of evidence does not release the contractor from its responsibilities if it is found that it does not hold the necessary rights, regardless of when and by whom this fact is revealed.

The contractor also warrants that it possesses the relevant rights or powers to execute the transfer and that it has paid or has verified payment of all due fees including fees due to collecting societies, related to the final *results*.

II.13.6. Quotation of works in the result

In the *result*, the contractor must clearly point out all quotations of existing works. The complete reference should include as appropriate, the following: name of the author, title of the work, date and place of publication, date of creation, address of publication on the internet, number, volume and other information that allows the origin to be easily identified.

II.13.7. Moral rights of creators

By delivering the *results*, the contractor warrants that the *creators* will not object to the following on the basis of their moral rights under copyright:

- (a) that their names be mentioned or not mentioned when the *results* are presented to the public;
- (b) that the *results* be divulged or not after they have been delivered in their final version to the contracting authority;
- (c) that the *results* be adapted, provided that this is done in a manner which is not prejudicial to the *creator's* honour or reputation.

If moral rights on parts of the *results* protected by copyright may exist, the contractor must obtain the consent of *creators* regarding the granting or waiver of the relevant moral rights in accordance with the applicable legal provisions and be ready to provide documentary evidence upon request.

II.13.8. Image rights and sound recordings

If natural persons appear in a *result* or their voice or any other private element is recorded in a recognisable manner, the contractor must obtain a statement by these persons (or, in the case of minors, by the persons exercising parental authority) giving their permission for the described use of their image, voice or private element and, on request, submit a copy of the permission to the contracting authority. The contractor must take the necessary measures to obtain such consent in accordance with the applicable legal provisions.

II.13.9. Copyright notice for pre-existing rights

When the contractor retains *pre-existing rights* on parts of the *results*, reference must be inserted to that effect when the *result* is used as set out in Article I.10.1, with the following disclaimer: '© — year — European Medicines Agency. All rights reserved. Certain parts are licensed under conditions to European Medicines Agency', or with any other equivalent disclaimer as the contracting authority may consider best appropriate, or as the parties may agree on a case-by-case basis. This does not apply where inserting such reference would be impossible, notably for practical reasons.

II.13.10. Visibility of contracting authority funding and disclaimer

When making use of the *results*, the contractor must declare that they have been produced under a contract with the contracting authority and that the opinions expressed are those of the contractor only and do not represent the contracting authority's official position. The contracting authority may waive this obligation in writing or provide the text of the disclaimer.

II.14. FORCE MAJEURE

II.14.1 If a party is affected by force majeure, it must immediately notify the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.14.2 A party is not liable for any delay or failure to perform its obligations under the contract if that delay or failure is a result of force majeure. If the contractor is unable to fulfil its contractual obligations owing to force majeure, it has the right to remuneration only for the services actually provided.

II.14.3 The parties must take all necessary measures to limit any damage due to force majeure.

II.15. LIQUIDATED DAMAGES

II.15.1. Delay in delivery

If the contractor fails to perform its contractual obligations within the applicable time limits set out in this contract, the contracting authority may claim liquidated damages for each day of delay using the following formula:

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

where

V is the price of the relevant purchase or deliverable or *result* or, failing that, the price specified in Article I.4.1;

d is the duration specified for delivery of the relevant purchase or deliverable or *result* or, failing that, the duration of *performance of the contract* specified in Article I.3.3 expressed in days.

Liquidated damages may be imposed together with a reduction in price under the conditions laid down in Article II.16.

II.15.2. Procedure

The contracting authority must *formally notify* the contractor of its intention to apply liquidated damages and the corresponding calculated amount.

The contractor has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the contractor submits observations, the contracting authority, taking into account the relevant observations, must *notify* the contractor:

- (a) of the withdrawal of its intention to apply liquidated damages; or
- (b) of its final decision to apply liquidated damages and the corresponding amount.

II.15.3. Nature of liquidated damages

The parties expressly acknowledge and agree that any amount payable under this Article is not a penalty and represents a reasonable estimate of fair compensation for the damage incurred due to failure to provide the services within the applicable time limits set out in this contract.

II.15.4. Claims and liability

Any claim for liquidated damages does not affect the contractor's actual or potential liability or the contracting authority's rights under Article II.18.

II.16. REDUCTION IN PRICE

II.16.1. Quality standards

If the contractor fails to provide the service in accordance with the contract ('unperformed obligations') or if it fails to provide the service in accordance with the expected quality levels specified in the tender specifications ('low quality delivery'), the contracting authority may reduce or recover payments proportionally to the seriousness of the unperformed obligations or low quality delivery. This includes in particular cases where the contracting authority cannot approve a *result*, report or deliverable as defined in Article I.5 after the contractor has submitted the required additional information, correction or new version.

A reduction in price may be imposed together with liquidated damages under the conditions of Article II.15.

II.16.2. Procedure

The contracting authority must *formally notify* the contractor of its intention to reduce payment and the corresponding calculated amount.

The contractor has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the contractor submits observations, the contracting authority, taking into account the relevant observations, must *notify* the contractor:

- (a) of the withdrawal of its intention to reduce payment; or
- (b) of its final decision to reduce payment and the corresponding amount.

II.16.3. Claims and liability

Any reduction in price does not affect the contractor's actual or potential liability or the contracting authority's rights under Article II.18.

II.17. SUSPENSION OF THE PERFORMANCE OF THE CONTRACT

II.17.1. Suspension by the contractor

If the contractor is affected by *force majeure*, it may suspend the *performance of the contract*. The contractor must immediately *notify* the contracting authority of the suspension. The *notification* must include a description of the *force majeure* and state when the contractor expects to resume the *performance of the contract*.

The contractor must *notify* the contracting authority as soon as it is able to resume *performance of the contract*, unless the contracting authority has already terminated the contract.

II.17.2. Suspension by the contracting authority

The contracting authority may suspend the *performance of the contract* or any part of it:

- (a) if the procedure for awarding the contract or the performance of the contract proves to have been subject *irregularities, fraud or breach of obligations*;
- (b) in order to verify whether the presumed *irregularities, fraud or breach of obligations* actually occurred.

The contracting authority must *formally notify* the contractor of the suspension and the reason for it. Suspension takes effect on the date of *formal notification*, or at a later date if the *formal notification* so provides.

The contracting authority must *notify* the contractor as soon as possible whether:

- (a) it is lifting the suspension; or
- (b) it intends to terminate the contract under Article II.18.1(f) or (j).

The contractor is not entitled to compensation for suspension of any part of the contract.

The contracting authority may in addition suspend the time allowed for payments in accordance with Article II.21.7.

II.18. TERMINATION OF THE CONTRACT

II.18.1. Grounds for termination by the contracting authority

The contracting authority may terminate the contract in the following circumstances:

- (a) if provision of the services under the contract has not actually started within 15 days of the scheduled date and the contracting authority considers the new date proposed, if any, unacceptable, taking into account Article II.11.2;
- (b) if the contractor is unable, through its own fault, to obtain any permit or licence required for *performance of the contract*;
- (c) if the contractor does not perform the contract in accordance with the tender specifications or is in breach of another substantial contractual obligation.
- (d) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation⁵;
- (e) if the contractor or any *related person* is subject to any of the situations provided for in points (c) to (f) of Article 136(1) or to Article 136(2) of the Financial Regulation.
- (f) if the procedure for awarding the contract or the *performance of the contract* prove to have been subject to *irregularities, fraud or breach of obligations*;
- (g) if the contractor does not comply with applicable obligations under environmental, social and labour law established by Union law, national law, collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU;
- (h) if the contractor is in a situation that could constitute a *conflict of interest* or a *professional conflicting interest* as referred to in Article II.7;
- (i) if a change to the contractor's legal, financial, technical, organisational or ownership situation is likely to substantially affect the *performance of the contract* or substantially modify the conditions under which the contract was initially awarded;
- (j) in the event of *force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the contract would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors;
- (k) if the contractor does not comply with the applicable data protection obligations resulting from Regulation (EU) 2016/679.

II.18.2. Grounds for termination by the contractor

The contractor may terminate the contract if:

⁵ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG

The contractor may terminate the contract if the contracting authority fails to comply with its obligations, in particular the obligation to provide the information needed for the contractor to perform the contract as provided for in the tender specifications.

II.18.3. Procedure for termination

A party must *formally notify* the other party of its intention to terminate the contract and the grounds for termination.

The other party has 30 days following the date of receipt to submit observations, including the measures it has taken to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

If the other party submits observations, the party intending to terminate must *formally notify* it either of the withdrawal of its intention to terminate or of its final decision to terminate.

In the cases referred to in points (a) to (d), (g) to (i) and (k) of Article II.18.1 and in Article II.18.2, the date on which the termination takes effect must be specified in the *formal notification*.

In the cases referred to in points (e), (f) and (j) of Article II.18.1, the termination takes effect on the day following the date on which the contractor receives *notification* of termination.

In addition, at the request of the contracting authority and regardless of the grounds for termination, the contractor must provide all necessary assistance, including information, documents and files, to allow the contracting authority to complete, continue or transfer the services to a new contractor or internally, without interruption or adverse effect on the quality or continuity of the services. The parties may agree to draw up a transition plan detailing the contractor's assistance unless such plan is already detailed in other contractual documents or in the tender specifications. The contractor must provide such assistance at no additional cost, except if it can demonstrate that it requires substantial additional resources or means, in which case it must provide an estimate of the costs involved and the parties will negotiate an arrangement in good faith.

II.18.4. Effects of termination

The contractor is liable for damage incurred by the contracting authority as a result of the termination of the contract including the cost of appointing another contractor to provide or complete the services, unless the damage was caused by the situation specified in Article II.18.1 (j) or in Article II.18.2. The contracting authority may claim compensation for such damage.

The contractor is not entitled to compensation for any loss resulting from the termination of the contract, including loss of anticipated profits, unless the loss was caused by the situation specified in Article II.18.2.

The contractor must take all appropriate measures to minimise costs, prevent damage and cancel or reduce its commitments.

Within 60 days of the date of termination, the contractor must submit any report, deliverable or *result* and any invoice required for services that were provided before the date of termination.

In the case of joint tenders, the contracting authority may terminate the contract with each member of the group separately on the basis of points (d), (e), (g) and (k) of Article II.18.1, under the conditions set out in Article II.11.2.

II.19. INVOICES AND VALUE ADDED TAX

Invoices must contain the contractor's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the contract reference and the Agency reference which may be communicated from time to time.

Invoices must indicate the place of taxation of the contractor (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

The contracting authority is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union.

The contractor (or leader in the case of a joint tender) must complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for *performance of the contract* are exempt from taxes and duties, including VAT.

II.20. PRICE REVISION

If a price revision index is provided in Article I.4.2, this Article applies to it.

Prices are fixed and not subject to revision during the first year of the contract.

At the beginning of the second and every following year of the contract, each price may be revised upwards or downwards at the request of one of the parties.

A party may request a price revision in writing no later than three months before the anniversary date of entry into force of the contract. The other party must acknowledge the request within 14 days of receipt.

At the anniversary date, the contracting authority must communicate the final index for the month in which the request was received, or failing that, the last provisional index available for that month. The contractor establishes the new price on this basis and communicates it as soon as possible to the contracting authority for verification.

The price revision is calculated using the following formula:

$$Pr = Po \times \left(\frac{Ir}{Io} \right)$$

where: Pr = revised price;

Po = price in the tender;

Io = index for the month in which the contract enters into force;

Ir = index for the month in which the request to revise prices is received.

II.21. PAYMENTS AND GUARANTEES

II.21.1. Date of payment

Payments are deemed to be effected on the date when they are debited to the contracting authority's account.

II.21.2. Currency

Payments are made in euros or in the currency provided for in Article I.7.

II.21.3. Conversion

The contracting authority makes any conversion between the euro and another currency at the daily euro exchange rate published in the Official Journal of the European Union, or failing that, at the monthly accounting exchange rate, as established by the European Commission and published on the website indicated below, applicable on the day when it issues the payment order.

The contractor makes any conversion between the euro and another currency at the monthly accounting exchange rate, established by the Commission and published on the website indicated below, applicable on the date of the invoice.

http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

II.21.4. Costs of transfer

The costs of the transfer are borne as follows:

- (a) the contracting authority bears the costs of dispatch charged by its bank;
- (b) the contractor bears the costs of receipt charged by its bank;
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

II.21.5. Pre-financing, performance and money retention guarantees

If, as provided for in Articles I.5 or I.6, a financial guarantee is required for the payment of pre-financing, as performance guarantee or as retention money guarantee, it must fulfil the following conditions:

- (a) the financial guarantee is provided by a bank or a financial institution approved by the contracting authority or, at the request of the contractor and with the agreement of the contracting authority, by a third party;
- (b) the guarantee shall have the effect of making the bank or financial institution or the third party provide irrevocable collateral security, or stand as first-call guarantor of the contractor's obligations without requiring that the contracting authority has recourse against the principal debtor (the contractor).

The contractor bears the cost of providing such guarantee.

Pre-financing guarantees must remain in force until the pre-financing is cleared against interim payments or payment of the balance. Where the payment of the balance takes the form of a debit note, the pre-financing guarantee must remain in force for three months after the debit note is sent to the contractor. The contracting authority must release the guarantee within the following month.

Performance guarantees cover compliance with substantial contractual obligations until the contracting authority has given its final approval for the service. The performance guarantee must not exceed 10 % of the total price of the contract. The contracting authority must release the guarantee fully after final approval of the service, as provided for in the contract.

Retention money guarantees cover full delivery of the service in accordance with the contract including during the contract liability period and until its final approval by the contracting authority. The retention money guarantee must not exceed 10 % of the total price of the contract. The contracting authority must release the guarantee after the expiry of the contract liability period as provided for in the contract.

The contracting authority must not request a retention money guarantee where it has requested a performance guarantee.

II.21.6. Interim payments and payment of the balance

The contractor (or leader in the case of a joint tender) must send an invoice for interim payment, as provided for in Article I.5 or in the tender specifications.

The contractor (or leader in the case of a joint tender) must send an invoice for payment of the balance within 60 days of the end of the period of provision of the services, as provided for in Article I.5 or in the tender specifications.

Payment of the invoice and approval of documents does not imply recognition of the regularity, authenticity, completeness and correctness of the declarations and information they contain.

Payment of the balance may take the form of recovery.

II.21.7. Suspension of the time allowed for payment

The contracting authority may suspend the payment periods specified in Article I.5 at any time by *notifying* the contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the contracting authority may cite for not being able to process an invoice are:

- (a) because it does not comply with the contract;
- (b) because the contractor has not produced the appropriate documents or deliverables; or
- (c) because the contracting authority has observations on the documents or deliverables submitted with the invoice.

The contracting authority must *notify* the contractor (or leader in the case of joint tender) as soon as possible of any such suspension, giving the reasons for it. In cases b) and c) referred above, the contracting authority shall notify the contractor (or leader in case of a joint tender) the time limits to submit additional information or corrections or a new version of the documents or deliverables if the contracting authority requires it.

Suspension takes effect on the date the contracting authority sends the *notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor (or leader in the case of a joint tender) may request the contracting authority to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph of this Article and the new document produced is also rejected, the contracting authority reserves the right to terminate the contract in accordance with Article II.18.1(c).

II.21.8. Interest on late payment

On expiry of the payment periods specified in Article I.5, the contractor (or leader in the case of a joint tender) is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus eight points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.21.7 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.21.1.

However, when the calculated interest is EUR 200 or less, it must be paid to the contractor (or leader in the case of a joint tender) only if it requests it within two months of receiving late payment.

II.22. NOT APPLICABLE

II.23. RECOVERY

II.23.1 If an amount is to be recovered under the terms of the contract, the contractor must repay the contracting authority the amount in question.

II.23.2. Recovery procedure

Before recovery, the contracting authority must *formally notify* the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, the contracting authority decides to pursue the recovery procedure, it must confirm recovery by *formally notifying* a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note.

If the contractor does not pay by the due date, the contracting authority may, after informing the contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the contractor by the European Medicines Agency;
- (b) by calling in a financial guarantee if the contractor has submitted one to the contracting authority;
- (c) by taking legal action.

II.23.3. Interest on late payment

If the contractor does not honour the obligation to pay the amount due by the date set by the contracting authority in the debit note, the amount due bears interest at the rate indicated in Article II.21.8. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the contracting authority receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.23.4. Recovery rules in the case of joint tender

If the contract is signed by a group (joint tender), the group is jointly and severally liable under the conditions set out in Article II.6 (liability). The contracting authority first claims the full amount to the leader of the group.

If the leader does not pay by the due date the whole amount and if the amount cannot be offset partially in accordance with Article II.23.2 (a), then the contracting authority may claim the full amount still due to any other member or members of the group by respectively *notifying* them with a debit note in conformity with the provisions laid down in Article II.23.2.

II.24. CHECKS AND AUDITS

II.24.1 The contracting authority and the European Anti-Fraud Office may check or require an audit on the performance of the contract. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf.

Such checks and audits may be initiated at any moment during the performance of the contract and up to five years starting from the payment of the balance.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the contracting authority. Audits are carried out on a confidential basis.

II.24.2 The contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance.

II.24.3 The contractor must grant the contracting authority's staff and outside personnel authorised by the contracting authority 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 to conduct such checks and audits. The contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

II.24.4 On the basis of the findings made during the audit, a provisional report is drawn up. The contracting authority or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of that deadline to submit observations.

On the basis of the final audit findings, the contracting authority may recover all or part of the payments made in accordance with Article II.23 and may take any other measure which it considers necessary.

II.24.5 In accordance with 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 (EU, Euratom) No 883/2013 of the European Parliament and the Council of 11 September 2013 concerning investigation conducted by the European Anti-Fraud Office , the European Anti-Fraud Office may carry out investigations, including on-the-spot checks and inspections, to establish whether there has been *fraud*, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the services and up to five years starting from the payment of the balance.

II.24.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939⁶ ('the EPPO') and, for the processing of personal data, the European Data Protection Supervisor, have the same rights as the contracting authority, particularly right of access, for the purpose of checks, audits and investigations.

⁶ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

ANNEX I

Tender specifications (reference No EMA-2018-30-CO of [*insert date*])

ANNEX II

Contractor's tender (reference No [complete] of [insert date])

The proof submitted by the contractor in its tender submission in relation to the selection and exclusion criteria is not included in hard copy in this annex but is retained in electronic format by EMA.

ANNEX III

Contractor's terms and conditions