



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## External expert contract

Contract number – [complete]

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

of the one part,

and

[full name and address of natural person]

(hereinafter referred to as "the Expert"),

of the other part,

### Have agreed

to enter into the terms and conditions below and the following Annexes:

**Annex I** – Code of Conduct

**Annex II** – Terms of Reference

**Annex III** – Declaration of absence of conflict of interests and of confidentiality

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

By signing this Contract, the Expert confirms that s/he has read, understood and accepted the Contract and all its obligations and conditions, including the Code of Conduct set out in Annex I, the Terms of Reference set out in Annex II and the Declaration of absence of conflicts of interest and of confidentiality set out in Annex III.

### CHAPTER 1 - GENERAL

#### Article 1 - Subject

**1.1.** *[The subject of the Contract is the evaluation of [proposals] [tenders] submitted in response to the call for [insert call reference]].*

*[The Expert must deliver a report on each [proposal and include recommendations] [tender and provide technical comments].]*

*The Expert may be asked to act as a 'rapporteur', for consensus discussions or meetings of evaluation committees.]*

OR

*[The subject of the Contract is assistance to the Agency with opinion and advice [insert full description of tasks]].*

## Article 2 – Working arrangements

2.1. The Expert’s work shall commence on [insert earliest starting date of work] and shall not exceed [insert number] working days. The Expert may not under any circumstances start work before the date on which this Contract enters into force in accordance with Article 22.

2.2. The indicative planning and number of working days for accomplishing the tasks are as follows<sup>1</sup>:

*OPTION 1 for in-situ evaluation:*

- *Up to [number] working days for attending a briefing, to take place at [insert address or web address for remote briefing] on [insert date].]*
- *Up to [number] working days for in-situ evaluation at [insert address].*
- *The Expert must submit the individual evaluation report by [number] days from the start of the evaluation work at the latest.*
- *The Expert must perform all tasks in accordance with Annex II.*

*OPTION 2 for remote evaluation:*

- *Up to [number] working days for attending a briefing, to take place at [insert address or web address for remote briefing] on [insert date].]*
- *Up to [number] working days for remote evaluation depending on the number of proposals assigned to the Expert in accordance with the following table.*
- *[Adapt the table as necessary]*

<b>Call [ref. no.]</b>	<b>Days counting towards fees</b>								-	-
[Action A: number of proposals]									-	-
[Action B: number of proposals]									-	-

- *The Expert must submit the individual evaluation reports by [number] days from the start of the evaluation work] at the latest.*
- *The Expert must perform all tasks in accordance with Annex II.*

*OPTION 3 for Experts assisting the Agency with opinion and advice:*

<sup>1</sup> The following are examples of options to be tailor-made according to the tasks to be conferred to the Expert.

- *Up to [number] working day[s] to perform the tasks between [insert starting date] and [insert end date] [including [number] of meeting days]*
- *The Expert must perform all tasks in accordance with Annex II.*

## **CHAPTER 2 – FEES, ALLOWANCES AND REIMBURSEMENT OF EXPENSES**

### **Article 3 – Fees**

- 3.1.** The Expert shall be paid a fee of EUR [complete] for each full day actually worked in accordance with Article 2.
- 3.2.** The total amount of the fees shall be calculated to the nearest half day.
- 3.3.** The maximum amount of fees paid under the Contract shall be limited to the maximum number of working days in accordance with Article 2.1.

### **Article 4 – Allowances and reimbursement of expenses**

- 4.1.** In addition to the fees specified in Article 3, the Agency will also reimburse expenses directly connected with the work specified in the Contract in accordance with the rules for reimbursement of expenses for delegates attending meetings at the European Medicines Agency with effect from 1 April 2017<sup>2</sup>.
- 4.2.** Other expenses will not be reimbursed, in particular:
  - costs of purchasing equipment or other material needed by the Expert to accomplish his/her tasks;
  - expenses already declared by the Expert under another EU or Euratom contract or grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget);
  - reckless or excessive expenses.

## **CHAPTER 3 – RIGHTS AND OBLIGATIONS OF THE PARTIES**

### **Article 5 – Performance of the Contract**

- 5.1.** The Expert must perform the Contract in compliance with its provisions and all legal obligations under applicable EU, international and national law.

The Expert must do so fully, within the set deadlines and to the highest professional standards. The Expert must, in particular, ensure compliance with:

  - the Code of Conduct (Annex I); and
  - applicable national tax and social security law.

The terms and conditions of this Contract do not constitute an employment agreement with the Agency.
- 5.2.** If the Expert cannot fulfil his/her obligations, s/he must immediately inform the Agency.

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<sup>2</sup>

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2017/03/WC500224061.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/03/WC500224061.pdf)

## Article 6 – Keeping records – supporting documentation

- 6.1. The Expert must keep records and other supporting documentation (original supporting documents) as evidence that the Contract is performed correctly and the expenses were actually incurred. These must be available for review upon the Agency's request.
- 6.2. The Expert must keep all records and supporting documentation for five years starting from the date of the last payment. If there are on-going checks, audits, investigations, appeals, litigation or pursuit of claims, the Expert must keep the records and supporting documents until these procedures end.

## Article 7 – Request for payment

- 7.1. Within 30 days of completion of days worked the Expert shall submit an admissible invoice with all supporting documents in PDF format by e-mail to the following address: [ema.vendorinvoices@ema.europa.eu](mailto:ema.vendorinvoices@ema.europa.eu). In particular, in order to be admissible the invoice must indicate the reference number of the Contract to which it refers and the following Agency reference which may be communicated from time to time: PO [complete]. Any invoice must give a breakdown of the fees.
- 7.2. In addition to the requirements laid down in Article 7.1, any invoice must clearly identify (a) the full name and address of the Expert; (b) the amount requested for payment; (c) the currency in which any amounts stated are denominated; and (d) the date of the invoice. Subject to verification by the Agency, payment shall be made no later than 30 days from receipt of the invoice.

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### *[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.']

## Article 8 – Bank account

- 8.1. Payments shall be made direct to the Expert's bank account denominated in Euro identified as follows:

Name of bank: [complete]  
Exact designation of account holder: [complete]  
Full account number including codes: [complete]  
IBAN code: [complete]  
SWIFT/BIC: [complete]

Any change to the Expert's bank account details (including any factoring arrangements entered into by the Expert in respect of sums due under the Contract) shall be communicated by letter to the Agency by the Expert; the Agency shall issue an acknowledgement.

## **Article 9 - Payments**

- 9.1.** The Agency will make payments within 30 calendar days of receiving the completed payment request(s) unless Article 13 applies.
- 9.2.** Payments are subject to the Agency's approval of deliverable(s) or report(s), and of the payment request(s). Approval does not mean recognition of compliance, authenticity, completeness or correctness of content.
- 9.3.** Payments will be made in Euros.
- 9.4.** Payments will be made to the bank account specified by the Expert in the payment request referred in Article 7.
- 9.5.** The Agency's payments are deemed to have been made on the date on which the Agency's account is debited.
- 9.6.** On expiry of the payment period specified in Article 9.1 and without prejudice to Article 13, the Expert 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 3.5 points. The reference rate is the rate in force on the first day of the month in which the payment period ends, as published in the C series of the Official Journal of the European Union.

The suspension of the payment periods in accordance with Article 13 may not be considered as a 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 actual payment as defined in Article 9.5.

However, when the calculated interest is lower than or equal to EUR 200, it must be paid to the Expert only upon request submitted within two months of receiving late payment.

Payments shall be executed in Euro according to the currency of the Contract as specified in Article 3.1. The Agency shall use the monthly accounting exchange rate established by the European Commission and published on its website, applicable on the day on which the payment order is issued by the Agency. The costs of the transfer shall be borne by the Agency.

## **Article 10 – Ownership and use of the results (including intellectual property rights)**

- 10.1.** The Agency must fully and irrevocably acquire the ownership of the results under this Contract including any rights in any of the results listed in this Contract, including copyright and other intellectual or industrial property rights, as well as all technological solutions and information contained within these technological solutions, produced in performance of the Contract. The Agency may exploit them as stipulated in this Contract. The Agency must acquire all the rights from the moment the results are delivered by the Expert and accepted by the Agency. Such delivery and acceptance are deemed to constitute an effective assignment of rights from the expert to the Agency.
- 10.2.** The Agency must acquire ownership of each of the results produced as an outcome of this Contract which may be used, for the following purposes of:

- (a) giving access upon individual requests without the right to reproduce or exploit, as provided for by Regulation (EC)1049/2001<sup>3</sup>;
- (b) storage of the original and copies made in accordance with this Contract;
- (c) archiving in line with the document management rules applicable to the Agency.

**10.3.** The Agency may use, publish, assign or transfer these results as it sees fit, without any limitations (geographical or other), unless intellectual property rights already exist.

## **Article 11 – Processing of personal data**

### **11.1. Processing of personal data by the Agency**

The Agency will process all personal data included in the Contract according to Regulation (EC) No 45/2001<sup>4</sup>.

Such data will be processed by the Head of Division of the Agency ('data controller') only to perform, manage and monitor the Contract.

The data may also be sent to persons or bodies responsible for monitoring or inspections in application of EU law.

The Expert has the right to access his/her personal data and to correct it. Any questions about or corrections to the Expert's personal data must be sent to the data controller.

The expert has the right of recourse to the European Data Protection Supervisor.

### **11.2. Processing of personal data by the Expert**

If the Contract requires the Expert to process personal data, the Expert may only act under the supervision of the data controller identified above in accordance with documented instructions. This is the case in particular for determining why personal data should be processed, what categories of data may be processed, who will have the right to access the data, and how the data subject may exercise its rights.

The Expert must put in place appropriate technical and organisational security measures to address the risks inherent to data processing and:

- (a) prevent unauthorised people from accessing computer systems that process personal data, and especially the:
  - (i) unauthorised reading, copying, alteration or removal of storage media;
  - (ii) unauthorised data input, disclosure, alteration or deletion of stored personal data;
  - (iii) unauthorised use of data-processing systems by means of data transmission facilities;
- (b) ensure that a data-processing system's authorised users can access only the personal data to which its access right refer;
- (c) record which personal data have been communicated by the Expert, when and to whom;
- (d) that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Agency;

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<sup>3</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145 of 31.5.2001).

<sup>4</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001).

- (e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or deleted without authorisation;
- (f) design its organisational structure in a way that meets data protection requirements.

**11.3** In accordance with Article 28(3) of Regulation (EU) No 679/2016, the Expert must, as a data processor, assist the controller in ensuring compliance with the obligations laid down by the applicable data protection legislation and in particular the obligation concerning notification of data breaches.

## **Article 12 – Checks, audits and investigations**

**12.1.** The Agency may carry out checks and audits to ascertain compliance with the proper implementation of the tasks (including assessment of deliverables and reports) under this Contract and whether the Expert is meeting his/her obligations.

It may do so throughout the Contract's validity and up to five years after the last payment is made. The Expert must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted. The Expert must allow access to sites and premises on which the tasks specified in this Contract are performed.

**12.2.** Under Regulation No 2185/96<sup>5</sup> and Regulation No 883/2013<sup>6</sup> (and in accordance with its provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the Contract or afterwards — 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 EU.

**12.3.** Under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 161 of the Financial Regulation No 966/2012<sup>7</sup>, the European Court of Auditors (ECA) may — at any moment during implementation of the Contract or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

**12.4.** Findings in checks, audits or investigations may lead to the reduction or rejection of fees, rejection of claims for allowances and expenses in accordance with Articles 14 and 15, or recovery of undue amounts in accordance with Article 16.

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

## **CHAPTER 4 - EFFECTS OF BREACHING CONTRACTUAL OBLIGATIONS**

### **Article 13 – Suspension of the payment time limit**

**13.1.** The Agency may at any point suspend the payment time limit if a request for payment cannot be processed because it does not comply with the Contract's provisions.

**13.2.** The Agency must notify the Expert of the suspension and the reasons for it.

**13.3.** The suspension takes effect on the day notification is sent by the Agency.

<sup>5</sup> 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 (OJ L 292, 15.11.1996).

<sup>6</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248).

<sup>7</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012).

**13.4.** If the condition for suspending the payment time limit as referred to in Article 13.1 is no longer met, the suspension will be lifted — and the remaining period will resume.

If the suspension exceeds two months, the Expert may ask the Agency if the suspension will continue.

**13.5.** If the payment time limit has been suspended due to the non-compliance of the reports or deliverables in accordance with Article 2 and the revised report or deliverables or payment request is not submitted or was submitted but is also rejected, the Agency may also terminate the Contract as referred to in Article 17.

## **Article 14 – Reduction of fees or rejection of fees, claims for allowances and expenses**

**14.1.** The Agency may reject:

- (a) (parts of) the fees if the Expert does not fulfil the tasks set out in Articles 1 and 2;
- (b) claims for allowances or expenses if they do not fulfil the conditions set out in Article 4.

**14.2.** The Agency may reduce the fee if the Expert is in breach of any of its other obligations under the Contract (including the obligations set out in the Code of Conduct).

**14.3.** The Agency must formally notify the Expert of its intention, include the reasons why, and invite him/her to submit any observations within 30 days of receiving notification.

If the Agency does not accept these observations, it will formally notify confirmation of the rejection or reduction.

## **Article 15 – Recovery of undue amounts**

**15.1.** The Agency may recover any amount that was paid but was not due under the Contract.

**15.2.** The Agency must formally notify the Expert of its intention, include the reasons why and invite him/her to submit any observations within 30 days of receiving notification.

If the Agency does not accept these observations, it will confirm recovery by formally notifying a 'debit note' that specifies the payment terms and date.

**15.3.** The Expert must repay the amount specified in the debit note to the Agency.

**15.4.** In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article 9.6. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.

**15.5.** In the event of failure to pay by the deadline specified in the request for reimbursement, the Agency may, after informing the Expert, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Expert also has a claim on the Agency that is certain, of a fixed amount and due.

## **Article 16 – Termination of the Contract**

**16.1.** The Agency may at any moment terminate the Contract if the Expert:

- (a) is not performing his/her tasks or is performing them poorly; or
- (b) has committed substantial errors, irregularities or fraud, or is in serious breach of its obligations under the selection procedure or under the Contract, including false declarations and obligations relating to the Code of Conduct.



**16.2.** The Agency must formally notify the Expert of its intention, include the reasons why and invite him/her to submit any observations within 30 days of receiving notification.

If the Agency does not accept these observations, it will formally notify confirmation of the termination.

**16.3.** The termination will take effect on the date the notification is sent by the Agency.

**16.4.** The Expert may at any moment terminate the Contract if s/he is not able to fulfil his/her obligations in carrying out the work required as referred to in Article 5.

**16.5.** The Expert must formally notify the Agency and include the reasons why by giving [15] days' notice.

**16.6.** The termination will take effect on the date the Agency will formally notify confirmation of the termination.

**16.7.** Only fees for days actually worked and expenses for travel actually carried out before termination may be paid subject to Article 14. The Expert must submit the payment request for the tasks already executed on the date of termination within [30] days from the date of termination.

**16.8.** On termination of the Contract, the Agency may hire another expert to carry out or finish the work. It may claim from the Expert all extra costs incurred while doing this, without prejudice to any other rights or guarantees it may have under the Contract.

## **Article 17 – Liability for damages**

The Agency cannot be held liable for any damage caused or sustained by the Expert or a third party during or as a consequence of performing the Contract, except in the event of the Agency's wilful misconduct or gross negligence.

## **Article 18 – Force majeure**

**18.1.** 'Force majeure' means any situation or event that:

- prevents either party from fulfilling its obligations under the Contract;
- was unforeseeable, exceptional and beyond the parties' control;
- was not due to error or negligence on its part and
- proves to be inevitable in spite of exercising due diligence.

**18.2.** A force majeure must be immediately and formally notified to the other party.

Notification must include details of the situation's nature, likely duration and expected effects.

**18.3.** The party faced with a force majeure will not be held in breach of its contractual obligations if the force majeure has prevented it from fulfilling them.

## **CHAPTER 5 – FINAL PROVISIONS**

### **Article 19 – Communication between the parties**

**19.1.** Communication under the Contract must:

- be made in writing and
- bear the Contract's number;

Formal notifications must be made by registered mail with return receipt or equivalent, or by equivalent electronic means.

**19.2.** Communications to the Agency must be sent to the following address:

[insert functional box or other e-mail addresses].

Communications to the Expert must be sent to the following address:

[insert e-mail address of Expert].

**19.3.** Electronic communication is considered to have been received by the parties on the day of dispatch of that communication provided it is sent to the e-mail addresses in Article 19.2.

Dispatch must be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party must immediately send again such communication to the e-mail address provided in this Contract. In case of unsuccessful dispatch, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Electronic communication must be confirmed by an original signed paper version of that communication if requested by any of the parties provided that this request is submitted without unjustified delay. The sender must send the original signed paper version without unjustified delay.

**19.4.** Formal notifications are considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

**19.5.** Mail sent using the postal services is deemed to have been received by the Agency on the date on which it is registered by the department responsible.

## **Article 20 – Amendments to the Contract**

**20.1.** In justified cases — and provided that the amendment does not entail changes to the Contract which would call into question the selection procedure — any party may request an amendment.

Amendments must be made before new contractual obligations are enforced.

**20.2.** The party requesting an amendment must formally notify the other party the requested amendment together with the reasons why.

The party receiving the request must formally notify its agreement or disagreement, within 30 days of receiving notification.

## **Article 21 – Applicable law and settlement of disputes**

**21.1.** This Contract is governed by Union law and is supplemented, where necessary, by the law of Belgium.

**21.2.** Disputes concerning the Contract's interpretation, application or validity that cannot be settled amicably must be brought before courts of Brussels.

## **Article 22 – Entry into force**

This Contract enters into force on the day on which the last party signs.

# Signatures

For the Expert,  
[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 - CODE OF CONDUCT FOR EXPERTS

## ARTICLE 1 - PERFORMANCE OF THE CONTRACT

1. The Expert works independently, in a personal capacity and not on behalf of any organisation.
2. The Expert must:
  - (a) carry out his/her work in a confidential and fair way;
  - (b) assist the Agency or relevant service to the best of his/her abilities, professional skills, knowledge and applying the highest ethical and moral standards;
  - (c) follow any instructions and time-schedules given by the Agency and deliver consistently high quality work.
3. The Expert may not delegate another person to carry out the work or be replaced by any other person.
4. If a legal entity participating in the [proposal] [tender] approaches the Expert during the course of performance of the Contract, he/she must immediately inform the Agency.

## ARTICLE 2 - OBLIGATIONS OF IMPARTIALITY

1. The Expert must perform his/her work **impartially and objectively**. To this end, the Expert is required to:
  - (a) inform the Agency of any conflicts of interest arising in the course of his/her work;
  - (b) confirm there is no conflict of interest for the work s/he is carrying out by signing a declaration (Annex III of the Contract).
2. **Definition of the conflict of interest:** a conflict of interest exists if an Expert:
  - (a) has any vested interests in relation to the questions upon which s/he is asked to give advice;
  - (b) or its organisation stands to benefit directly or indirectly, or be disadvantaged, as a direct result of the work carried out;
  - (c) is in any other situation that compromises his/her ability to carry out his/her work impartially.

The Agency will confirm in writing whether a conflict of interest exists, taking account of the objective circumstances, available information and related risks when the Expert is in any other situation that could cast doubt on his/her ability to carry out his/her work, or that could reasonably appear to do so in the eyes of an external third party.

3. **Consequences of a situation of conflict of interest:**
  - (a) If a conflict of interest is reported by the Expert or established by the Agency, the Expert must not carry out the work;
  - (b) If a conflict becomes apparent in the course of his/her work, the Expert must inform the Agency immediately. If a conflict is confirmed, the Expert must stop carrying out his/her work. If necessary, the Expert will be replaced.

### ARTICLE 3 - OBLIGATIONS OF CONFIDENTIALITY

1. The Agency and the Expert must treat confidentially any information and documents, in any form (i.e. paper or electronic), disclosed in writing or orally in relation to the performance of the Contract.
2. The Expert undertakes to observe strict **confidentiality** in relation to his/her work.

To this end, the Expert must not use or disclose, directly or indirectly, confidential information or documents for any purpose other than fulfilling his/her obligations under the Contract without prior written approval of the Agency.

In particular, the Expert:

- i. must not discuss his/her work with others, including other experts or Agency or relevant service staff not directly involved in his/her work;
  - ii. must not disclose:
    - any detail of his/her work and its outcomes for any purpose other than fulfilling his/her obligations under the Contract without prior written approval of the Agency;
    - his/her advice to the Agency on his/her work to any other person (including colleagues, students, etc.);
  - iii. must not communicate with any participating legal entity on any matter relevant to the [proposal] [tender] even after the conclusion of the tender.
3. If material/documents/reports/deliverables are made available either on paper or electronically to the Expert who then works from his/her own or other suitable premises, he/she will be held personally responsible for maintaining the confidentiality of any documents or electronic files sent and for returning, erasing or destroying all confidential documents or files upon completing his/her work as instructed.
  4. If his/her work takes place in premises controlled by the Agency, the Expert:
    - (a) must not remove from the premises any copies or notes, either on paper or in electronic form
    - (b) will be held personally responsible for maintaining the confidentiality of any documents or electronic files sent, and for returning, erasing or destroying all confidential documents or files on completing his/her work as instructed.
  5. If the Expert seeks further information (for example through the internet, specialised databases, etc.) to complete his/her work, he/she:
    - (a) must respect the overall rules for confidentiality for obtaining such information;
    - (b) must not contact third parties without prior written approval of the Agency.
  6. These confidentiality obligations are binding on:
    - (a) the Agency (see Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community)<sup>8</sup>
    - (b) the Expert during the performance of the Contract and for five years starting from the date of the last payment made to the Expert unless:
      - i. the Agency agrees to release the Expert from the confidentiality obligations earlier;
      - ii. the confidential information becomes public through other channels;
      - iii. disclosure of the confidential information is required by law.

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<sup>8</sup> OJ 45, 14.6.1962, p. 1385.

## ANNEX II - TERMS OF REFERENCE

1. [Name of the experts' group: *[insert name]*]
2. Context and background information
3. Purpose, objectives and scope
4. Working approach and methodology
5. [Distribution of work among the Experts]
6. Meetings, reporting and deadlines
7. Deliverables and conditions to submit request for payments

## **ANNEX III – DECLARATION OF ABSENCE OF CONFLICT OF INTERESTS AND OF CONFIDENTIALITY**

### **Conflict of interests**

I, the undersigned [FAMILY NAME, first name], having been appointed as an Expert for the abovementioned call, declare that I am aware of Article 41 of the Financial Regulation applicable to the budget of the European Medicines Agency<sup>9</sup>, which states that:

*“1. Financial actors within the meaning of Chapter 2 of this Title and other persons involved in budget implementation and management, including acts preparatory thereto, audit or control shall not take any action which may bring their own interests into conflict with those of the Agency.*

*Where such a risk exists, the person in question shall refrain from such action and shall refer the matter to the competent authority who shall confirm in writing whether a conflict of interests exists. Where a conflict of interest is found to exist, the person in question shall cease all activities in the matter. The competent authority shall take any further appropriate action.*

*2. For the purposes of paragraph 1, a conflict of interest exists where the impartial and objective exercise of the functions of a financial actor or other person, as referred to in paragraph 1, is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other shared interest with a recipient. ”*

I hereby declare that I do not fall under any of the following circumstances in which a conflict of interests might exist. I confirm that, if I discover before or during the performance of my tasks that a conflict of interests exists, I will declare it immediately to the Agency.

### **1. Disqualifying conflict of interests:**

- Direct benefit in case of advice on development of a new policy;
- Involvement in the preparation of the [proposal] [tender];
- Direct benefit in case of acceptance of the [proposal] [tender];
- Close family relationship with any person representing a participating organisation in the [proposal] [tender];
- Director, trustee or partner of a participating organisation;
- Current employment by a participating organisation;
- Current involvement in a contract or collaboration with a participating organisation;
- Any other situation that compromises my ability to evaluate the [proposal] [tender] impartially, including but not limited to, any situation arising from economic interests, family or emotional interests, political or national affinity.

### **2. Potential conflict of interests:**

- Employment by one of the participating organisations within the previous three years;
- Involvement in a contract or collaboration with a participating organisation within the previous three years;
- Any other situation that could cast doubt on my ability to evaluate the [proposal] [tender] impartially, or that could reasonably appear to do so in the eyes of a third party (*Ex. Past or current personal relationships, nationality, political affinity, etc.*).

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<sup>9</sup> EMA/MB/789566/2013, applicable from 01/01/2014.

I hereby declare that I fall under one or more of the above circumstances (please specify which and explain)\*:

*\*Ex. In case of employment by a structure including different departments or institutes, please specify the degree of autonomy between them.*

I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

**Confidentiality and personal data protection**

I confirm that I have read, understood and accepted the Code of Conduct for Experts established in Annex I to the Contract sent by the Agency.

I also confirm that I will keep all matters entrusted to me confidential and will process the personal data I receive only for the purposes of the performance of the present Contract. If unnecessary or excessive personal data are contained in the documents submitted during the implementation of the Contract I will not process them further or take them into account for the implementation of the Contract. I will not communicate outside [the evaluation committee] [the expert's group] any confidential information that is revealed to me or that I have discovered. I will not make any adverse use of information given to me.

Expert: [insert full name]

Date:

Signature: