European Medicines Agency

London, 28 June 2006
Doc. Ref.: EMEA/171058/2006

Technical Specifications For Open Invitation to Tender
No. EMEA/2006/32/DIR
External Member(s) of EMEA's Audit Advisory Committee

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1. Title of the Invitation to tender

This document contains the Technical Specifications for the Open Invitation to Tender no. EMEA/2006/32/DIR for external members of EMEA's Audit Advisory Committee (hereinafter also called 'AAC' or 'the Committee').

Contract Notices have previously been published in the Official Journal of the European Union S109 of 8 June 2005, which included three lots, and in the Official Journal S245 of 21 December 2005. Three contracts have been awarded under Lots 2 and 3 of this open procedure. Lot 1 of this open procedure has been cancelled on the two previous occasions and notices have been published in the Official Journal of the European Union to this effect.

EMEA has republished a contract notice for lot 1, (covering Accounting and/or financial audit and/or business consultancy) as it considers that it may require 1 or more additional external member(s) for its Audit Advisory Committee, covering the areas of expertise detailed below (please see point 3 of this Technical Specifications).

One contract is expected to be concluded. Tenderers who have already been offered a contract through the open tender procedure EMEA/2005/16/DIR, published in the Official Journal of the European Union S109 of 8 June 2005, or EMEA/2005/137/DIR, published in the Official Journal of the European Union S245 of 21 December 2005, will not be considered eligible to participate in this new tender since they are already members of the AAC.

Only responses from individuals will be accepted, since appointment will be on a personal basis. Therefore, companies, academic institutions and any other partnerships or institutions are excluded from this tender, although they may put forward individuals that, if appointed, will not represent the organisation.

2. Objectives and Context of the Invitation to Tender

The European Medicines Agency is an international organisation based in Canary Wharf in the Docklands area of London (E14).

EMEA was established in 1995 when a new European system for the authorisation of medicinal products came into effect. EMEA is an Agency of the European Union and has its own legal personality. EMEA's budget is subject to checks and audits by the European Court of Auditors.

The work of EMEA is to co-ordinate the existing scientific resources of the EU Member States in order to evaluate and supervise medicinal products for both human and veterinary use throughout the whole of the European Union. The Agency also gives scientific advice to research-based companies in the development stage of new medicinal products and also in the form of guidelines on quality, safety and efficacy testing requirements.

The Audit Advisory Committee was established in 2004 and is an important part of EMEA's governance structure, with its main task being to provide the Executive Director and other

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management with the best possible advice on issues pertaining to integrated quality management, risk management, internal controls and internal audit. The working language of the Agency and of the Committee is English.

3. Subject of the Tender

EMEA considers that it may require one or more additional external member(s) of its Audit Advisory Committee, with the area of expertise described below. One contract is expected to be awarded on an individual basis to coincide with the mandate of the Audit Advisory Committee. The mandate has commenced in 2006 and will end in December 2008.

3.1. Basic requirements

The Agency wants to obtain consultancy and/or advice from highly experienced individuals. Therefore, tenderers shall comply with certain basic requirements regarding the time and nature of their experience and their level of education.

Tenderers must comply with the following basic requirements:

3.1.1. Holding a university degree or equivalent national qualification entitling him/her to undertake post-graduate studies.

3.1.2. Have at least 15 years' professional experience after obtaining their degree. At least seven years of that professional experience must have been gained in the areas of accounting and/or financial auditing and/or business consultancy. At least five of them must have been at a senior level.

3.1.3. Knowledge of integrated internal audits (preferably of both the financial and operational process aspects) and audit methodology.

3.1.4. Competence in the area of governance, being aware of the latest developments in the field, both at European and international level.

3.1.5. General knowledge of internal control, including risk management, and integrated (quality) management systems and benchmarking, to ensure compliance and continual improvement.

3.1.6. Working knowledge of English, as it is the working language of the EMEA and the Committee.

3.2. Desirable requirements

There are also some additional requirements that the Agency would consider to be of value for the type of advice and/or consultancy required from the tenderers. These are:

3.2.1. Working experience with/in Audit Committees.

3.2.2. Professional/vocational qualifications or certifications within their area of expertise (such as chartered accountant, certified auditor or similar, both at national and international level).

3.2.3. Knowledge of the institutions of the European Union, its main policies and procedures.

3.2.4. Experience of working within a multicultural environment.

3.2.5. Knowledge of additional European languages, as the Agency works in a multicultural and multilingual environment, with partners in all Member States and European Economic Area countries (Norway, Iceland and Liechtenstein).

Tenderers are requested to submit their CVs and provide documentary evidence in support thereof (employment contracts, references etc.).

Tenderers must be able to prove that their tender submission will not cause or be seen to cause any conflict of interests (please see Annex I). If a contract is awarded, tenderers will be requested to sign the declaration of interest and confidentiality undertaking included as Annex III.

The Audit Advisory Committee meets at the EMEA premises in London, UK, four times per year, with the possibility of additional meetings if deemed necessary. Meetings are scheduled one year in advance and last one working day. Preparatory work before the meeting and finalisation work after the meeting are estimated to require at least two additional working days.

The Evaluation Committee for the tender will prepare a shortlist of tenderers, together with the reasons for their recommendations.

4. Participation in the tender

Participation in this tendering procedure shall be open on equal terms to all natural persons coming within the scope of the Treaties and to all natural persons in a third country which has a special agreement with the European Communities in the field of public procurement under the conditions laid down in that agreement.

Tenderers must be nationals of the EU member states or Iceland, Norway or Liechtenstein or any national of a country which has ratified the Plurilateral Agreement on Public Procurement concluded within the World Trade Organisation.

Sub-contracting is not permitted. Successful tenderers are appointed on a personal basis and may not nominate alternates.

5. Additional documentation available to tenderers

Further information about the work of EMEA can be obtained on its website: http://www.emea.eu.int.

Further information about the EMEA's corporate governance structure can also be obtained at the EMEA's webpage.

6. Information Visit

N/A

7. Variants

N/A

8. Estimated contract volume

It is estimated that members will spend, at least, one day on preparation for each meeting, one day on the meeting and one additional day after the meeting. Four annual meetings are planned, and a contingency for one ad-hoc meeting per year is included. Over the mandate of the committee, this will amount to a maximum of 39 days of consultancy. A margin of 12 days will be added to the contract and honoured if required (e.g. by specific tasks), thus bringing the maximum to 51 days for the contract.

9. Price

9.1 Currency of Tender

All amounts and prices are indicated in Euro.

9.2 All-inclusive prices

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include all related travel, subsistence etc). No expenses incurred in the performance of the services will be reimbursed separately by EMEA.

However, prices should be indicated exclusive of any VAT or similar taxes.

Tenderers must submit a daily rate in Euro, which is all-inclusive.

9.3 Price Revision

The price will remain fixed for the full contract period and will not be subject to revision.

9.4 Costs involved in preparing and submitting a tender

EMEA will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

9.5 Period of validity of the tender

Tenders must be valid for a period of six months from the date of submission of the tender.

9.6 Protocol on the Privileges and Immunities of the European Communities.

EMEA is, as a rule, exempt from all taxes and duties, including value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities.

10. Payment arrangements

Payments under the contract shall be executed only if the contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted, including specified deliverables. Payment shall be made quarterly in arrears, on the basis of invoices submitted by the contractor. Invoices must detail the work done for the Committee and the hours devoted to it.

11. Contractual details

A draft contract is attached to these Technical Specifications as Annex IV.

EMEA expects to conclude one individual contract for to coincide with the length of the mandate of the Audit Advisory Committee, 2006-2008 inclusive. The contract may be renewed once for an additional mandate of the Committee.

12. Exclusion criteria

Tenderers shall be excluded from participation in this procurement procedure if:

- They are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

- They have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

- They have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;

- They have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;

- They have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;

- Following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

- Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

  - Cannot comply with EMEA's policy on conflict of interest or on confidentiality (cf. annexes I and II). The members of the Audit Advisory Committee are appointed on a personal basis. If selected, tenderers will be required to sign a declaration of interests and confidentiality undertaking. A model declaration has been included as Annex III.
  - Are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information.

Tenderers must complete the declaration in Annex V in relation to Exclusion Criteria and provide all the supporting documentation indicated in this Annex, when applicable. In case of doubt over the documents to be presented as supporting documentation, the tenderers may contact the person in charge of the tender.

13. Selection Criteria: Financial and Economic Capacity

Tenderers must provide a sworn signed declaration stating the total annual turnover related to the field identified in point 3 in the past three years. When possible, the declaration must be accompanied by relevant official documents (such as tax declarations).

14. Selection Criteria: Technical and Professional Capacity

Tenderers are requested to provide the following documentation to enable an assessment of their technical and professional capacity:

- Proof of authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

- Photocopy of university degree or equivalent national qualification entitling him/her to undertake post-graduate studies.

- Proof of 15 years of professional experience acquired after obtaining their degree, as required in point 3.1.2 above. Proof of professional experience must state both the start and end dates and the exact duties performed.

Photocopies of all the relevant documents are accepted for the application, but originals or certified copies must be presented before the contract is signed by the Agency. Documentation submitted as part of the tender will not be returned to the tenderers.

EMEA wishes to inform tenderers that it applies the European Union policy of equality between men and women.

15. **Award Criteria**

The contract will be awarded to the most economically advantageous tender (or best value for money).

The award criteria that will apply to this tender are as follows:

1. Proven relevant professional experience, see point 3.1 above.	30%
2. Previous proven experience with Audit Committees' work.	15%
3. Relevant certification from professional bodies and/or membership of relevant professional organisations.	10%
4. Additional proven qualifications, experience or skills related to the work of the Committee. Proven command of English and knowledge of additional languages Proven knowledge of the institutions of the European Union, its main policies and procedures.	15%
5. Price (all-inclusive professional fees)	30%

The Evaluation Committee will first examine criteria 1 to 4. Criteria 5 will then be examined.

Provisional points will be awarded to make a first shortlist of tenderers. If the Evaluation Committee feels it is needed, it will ask to have an interview with some of the tenderers, which will serve to reassign the points given for each criterion. Should an interview be requested, it will be mandatory for the tenderer to participate. Should any tenderer who is requested to attend an interview decline to do so, he/she will be eliminated.

When no interviews are conducted, the points awarded in the first phase by the Evaluation Committee will be final.

Those tenderers who do not meet a minimum score of 60 points in the award criteria will be eliminated.

Tenderers are requested to provide the following documentation to enable an assessment of the award criteria:

- Curriculum Vitae (CV), clearly showing the qualifications and professional experience. The CV must describe the title of the posts occupied, the nature of professional experience.

- Proof of experience with Audit Committees, when applicable.

- Separate sheet describing previous experience relevant to the requirements of membership of the Audit Advisory Committee (maximum 400 words). For details of what is considered relevant experience, please refer to points 3.1.3, 3.1.4 and 3.1.5 of this document.

- Proof of the nature of professional experience, describing the posts occupied and details of the tasks performed, including achievements, and the level of the experience (management position, management committee or audit member, consultancy services, etc.).

- Separate sheet describing how the knowledge of the institutions of the European Union, its main policies and procedures has been acquired (maximum 200 words).

- References from previous employers/contractors are welcome and must clearly state the name and post of the signatory, together with the contact details and a signed statement of independence by the signatory (cf. Annex VII). By signing the documents, the signatories authorise the Agency to contact them to check any details given in the candidature.

- Proven knowledge of English at sufficient level, documented either through relevant diplomas, educational background or professional experience. Please provide a brief explanation as necessary.

- Details of registration with a professional organisation, relevant to the duties described in point 3 of this tender.

- Details of any vocational/professional qualifications or certifications in the fields described in point 3 of this tender. Certifications awarded by national bodies (e.g. certified accountants according to their Member States requirements) should be complemented with a brief description of the requirements at national level (years of professional experience, university degrees…)

- A financial tender giving the proposed all-inclusive daily price exclusive of VAT for provision of the services as described in this document.

Photocopies of all the relevant documents are accepted for the application, but originals or certified copies must be presented before the contract is signed by the Agency. Documentation submitted as part of the tender will not be returned to the tenderers.

16. Tender to be submitted

In order to assess each tenderer according to the above-mentioned criteria, the tenderers must submit the following information:

- A cover letter enclosing the tender and signed and dated by the tenderer.

- An information sheet on the tenderer indicating:
  - the name and registered business address, or home address, if the former is not applicable;
  - any other different current or previous name;
  - the name and contact details of the person who may be contacted with any queries regarding this tender;

- Completed questionnaire in Annex V relating to Exclusion Criteria AND supporting documentation.

- Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above).

- Documentation requested to enable assessment of Award Criteria (point 15 above). **To be submitted in a separate binder or folder, which must be clearly labelled**, a detailed financial tender with all-inclusive daily rate, and exclusive of VAT, signed by an authorised representative of the tenderer.

- A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information in response to this tender could result in the tenderer being excluded from future tenders for contracts with EMEA.

- An undertaking to inform EMEA promptly following any matter that would alter or add to any of the information given in response to this tender.

- A declaration stating that the tenderer is willing and able to dedicate sufficient time to provide high quality contribution to the work of the Audit Advisory Committee.

- Tenderers are requested to make use of the checklist given in Annex VI to ensure that no enclosure has been omitted in their tender.

Annex I – Rules on conflict of interest

EMEA Guidance on Conflicts of Interests

1. Legal basis

Article 63 (2) of Council Regulation (EC) No 726/2004 lays down provisions which require that

> "Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered into a register held by the Agency which is accessible to the public, on request, at the Agency's offices. "
>
> The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts.

By analogy and in accordance with the provisions of the Regulations and rules applicable to officials and other servants of the European Communities (the 'Staff Regulation'), the Executive Director extends these requirements to all EMEA staff.

2. Who should declare?

- All Management Board, scientific committee and working party members including official observers
- All European experts listed by the EMEA
- All EMEA staff. The EMEA Code of Conduct will apply by analogy to all visiting staff (e.g. national experts on secondment, trainees, interims, conference hostesses or visiting experts)
- Observers (Norway, Iceland and Lichtenstein) to the Management Board are treated as full members for the purposes of the Declaration of Interest.

Whilst Council Regulation (EC) No 726/2004 specifically refers to interests held in the pharmaceutical industry, members of EMEA staff are bound under the Staff Regulation, by the obligation to act with integrity and loyalty. This annex offers additional guidance on identifying interests that could present conflicts.

3. What to declare?

Each individual is responsible for the declaration of his interests.

What is an interest?

There are essentially three categories of interests:

(a) <u>Financial interests</u>
Any financial interests in the pharmaceutical industry, including holding of stocks and shares, stock options, equity, bonds, partnership interests[1] in the capital of a pharmaceutical company, one of its subsidiaries or a company in the capital of which it has a holding.

The holding of financial interests connected with a pension scheme previously contracted prior to the nomination as Committee or working party member or expert or appointment as EMEA staff and/or

[1] When declaring financial interests e.g. stocks and shares, only the kind, number and company name need to be stated.

interests in non-nominal unit trusts or similar arrangements would not, in principle, have particular consequences providing the individual has no influence on financial management.

(b) Work carried out for the pharmaceutical industry

During the preceding five years, all activities performed for or on behalf of pharmaceutical companies[1], whether or not these activities have been subject to regular or occasional remuneration in cash or kind, including:

- Participation in the internal decision-making of a pharmaceutical company (e.g. Board membership, executive or non executive directorship)
- Permanent or temporary member of the personnel of a pharmaceutical company. Other activities performed within a pharmaceutical company (e.g. academic grants, traineeship) are also subject to declaration
- Work contracted out by pharmaceutical companies, through consultancy or otherwise.

(c) Other links with pharmaceutical industry

During the preceding five years, all assistance and support received from industry[2]**,** whether associated with direct or indirect pecuniary or material benefits, including:

- Grants for study or research allocated by the industry
- Fellowships or sponsorships endowed by pharmaceutical industry.

(d) Links with other industries relevant to the nature of the work

During the preceding five years, all assistance and support received from industry, whether associated with direct or indirect pecuniary or material benefits, including:

- Grants for study or research allocated by the industry
- Fellowships or sponsorships endowed by the industry, e.g. IT industry, manufacturing company, Directorship of recruitment agency.

What are direct and indirect interests?

Interests can be direct or indirect depending on their likely or potential impact on the individual's behaviour at a given point in time.

Direct interests: Interests of personal benefit to the individual at any point in time, likely to influence or give the appearance of influencing his behaviour (e.g. employment with a pharmaceutical company, financial interests of a certain magnitude)

> It follows from Article 63 (2) of Council Regulation (EC) No 726/2004 that the holding of direct interests is in principle incompatible with being a member of Management Board, Committee or working party and, by analogy, of EMEA staff.
> In order to remain in office, the individual concerned would have to take appropriate action to suppress the conflict.

Indirect interests: Other interests that may have some influence over the individual's behaviour and therefore have to be neutralised.

> Article 63 (2) of Council Regulation (EC) No 726/2004 does not prohibit the holding of indirect interests and these are subject to public declaration. Indirect interests should be scrutinised so that precautions can be taken in order to ensure impartiality of decision taking. Appropriate actions could include precluding the individual from certain functions or tasks (e.g. rapporteur, expert, project manager) or requiring abstention from part of the relevant proceedings or voting in the meetings of the scientific committees and/or working parties.

[1] Company name, position held and activities performed should be set out clearly and precisely. Where activities relate to specific product(s), declarations must indicate product name and nature of the work.

[2] For example a staff member formerly in an IT company and who was now employed at the EMEA in the IT sector and where the company had links with the IT sector or was awarded contracts should declare this former employment as an indirect interest.

4. When to declare?

The declaration of interests' forms has been revised with a view to provide more guidance to all parties concerned on how to complete and update them. The new forms are attached to this Annex.

Initial declaration

Upon nomination as committee member or expert or appointment as EMEA staff member, each individual is required to fill out a declaration of interests' form.

Appointment as rapporteur or expert

Members of scientific committees and European experts should not accept appointment as (co)-rapporteur or expert for an application or referral, etc. if it becomes apparent that there could be a conflict of interest because that person has in anyway been associated with the studies contained in the dossier.

Spontaneous declarations

Under Article 63 (2) of Council Regulation (EC) 726/2004 if during meetings or working groups and in addition, this code specifies assessment or advisory work, a potential conflict becomes apparent to a member, rapporteur or expert, then it must be declared to the chairperson immediately who will notify the Secretariat and appropriate action agreed to. This, in particular, would include a situation where an expert is asked to assess data of his own research or his own expert report in a dossier. These declarations shall be made available to the public.

If, at any time, in the course of their duties EMEA staff members become aware any potential conflict they must immediately inform their Head of Unit who will determine any appropriate action.

Updates

Declarations of interests must be updated at least annually under Article 63 (2) of Council Regulation (EC) No 726/2004 or as soon as an update is required for any new situation arising. As part of the new experts' database, electronic updates are available to facilitate exchange of information.

Staff members update their declarations annually. Management Board members provide a declaration at the start of the Management Board mandate of the individual and at the beginning of the official mandate of the Management Board and annually thereafter.

5. Operational aspects

Tasks of EMEA Secretariat

The EMEA Secretariat, under the direct responsibility of the Head of Unit concerned, undertakes the following:

- Remind all parties concerned of their obligation to declare the interests;
- Assess and monitor regularly declarations and make preliminary appraisal of compatibility of interests declared with general or specific office or duties of the individuals concerned;
- Initiate and facilitate dialogue within the appropriate forum (e.g. committee or working party).

In accordance with Article 63 (2) of Council Regulation (EC) No 726/2004, the EMEA Secretariat ensures, under the responsibility of the Head of Administration in respect of EMEA staff only, the availability of all declarations and updates for public consultation at the Agency's offices. For Management Board members, all committee, working party members and experts the availability of declarations and updates is available for public consultation at the Agency's offices on contacting Central Information Group - Post Authorisation for experts and Executive Support Sector for the Management Board.

Obligations of individuals concerned

Management Board, Committee and working party members, European experts and staff members (Article 14 of the Staff Regulations) have a primary obligation to disclose at any time the existence of possible conflict of interests that may place the impartiality of EMEA at risk. The individual should state, in particular, the type and nature of interests, specifying whether they are general or relate to a specific product or other tender, recruitment etc. If the conflict is product-related, prior involvement of rapporteurs and experts in relation to competing products as well as past and current links with companies.

Procedure to review the declaration of interest

In the case of EMEA staff anyone wishing to review their entry on the declarations of interest listing should contact the Head of Administration to make an appointment to review the listings. Members of EMEA staff wishing to review any other declaration of interest should consult with their own or, if they so wish, another Head of Unit.

In the case of Management Board members, Committee or working party members and experts, the primary contact persons are Central Information Group - Post Authorisation for experts and Executive Support Sector for the Management Board

Meeting proceedings

Article 63 (2) of Council Regulation (EC) No 726/2004 lays down provisions which require that

> 'Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interest which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.'

Individuals have the primary responsibility to spontaneously declare any conflict of interest at all times.

However meeting chairpersons of all meetings should periodically – at the start of each meeting or at least every 6 months – remind members and experts of their obligation to update their declarations.

Particular precautions should be taken in the case of ad hoc expert groups or other situations where conflicts of interests are likely, in which case a systematic reminder should be made at the beginning of every such meeting.

Reminders and discussions should be recorded in minutes of meetings together with detailed statements on conflicts.

On the basis of the type and nature of interests noted, meetings could consider various options, including:

- Fundamental incompatibility with membership of the group
- Incompatibility with the performance of certain functions or tasks (e.g. rapporteurship, expert)
- Temporary exclusion from the meeting
- Abstention from the debate and/or the vote.

The following documents are standard forms for the declaration of interests by EMEA staff and for members of the Management Board, scientific committees, working parties and European experts.

Annex II – Rules on confidentiality

EMEA Guidance on Confidentiality and Discretion

The EMEA is a public body of the European Union. It has been entrusted with the important duty of the evaluation of medicinal products (both human and veterinary) on behalf of consumers, patients and the pharmaceutical industry. Members of the Management Board, members of scientific committees and working parties, experts and EMEA staff members, must treat information on the Agency's work with the utmost discretion and confidentiality.

The EMEA faces potentially conflicting obligations of public access to documents and transparency and the need to respect confidentiality of information that the Agency holds in its role as regulator.

Under Article 73 of Council Regulation (EC) No 726/2004 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 shall apply to documents held by the Agency.

A significant amount of information is available through the EMEA website (http://www.emea.eu.int). The EMEA decision on rules on access to documents was adopted on 7 October 2004 by the Management Board (EMEA/MB/67083/04 (replacing the previous decision of the Executive Director of 11 March 2004).

This access to information, however, is balanced by the rules of professional secrecy for EMEA staff and experts and the obligation to respect European and international laws on the protection of data in the pharmaceutical sector.

1 *Duty of confidentiality*

The respect of confidentiality is an essential part of the relationship between the EMEA, European institutions, Member States and pharmaceutical companies. The EMEA recognises that its staff, members of scientific committees, working parties and experts have access to commercially confidential information.

Article 76 of Council Regulation (EC) No 726/2004 also sets out a duty of confidentiality for members of the Management Board, scientific committees working parties, experts and EMEA staff

Article 17 of the Regulations and Rules applicable to officials and other servants of the European Communities (Staff Regulations) binds staff members to a general duty of confidentiality and to exercise the greatest discretion even after leaving the service of the EMEA. The attention of new members of staff is drawn to the provisions contained in the Staff Regulations. They acknowledge in writing that they have read and understood the relevant articles, on the confidentiality provisions in the Staff Regulations and the disciplinary measures. Staff members are also required on separation from the EMEA to sign a letter of undertaking regarding confidentiality and discretion.

Interim staff, trainees, national experts on secondment, visiting experts, persons participating in a work experience programme, consultants are all required to sign a confidentiality undertaking.

EMEA staff and others are advised to exercise care when answering questions so as not to supply information to third parties regarding specific products where this information is not public. Discretion should be exercised when discussing professional work with third parties including family and friends and with colleagues or third parties in a public place e.g. EMEA restaurant, public transport. The provenance of the party putting a question should always be ascertained and questions should be put in writing where possible. Common sense must be applied regarding indirect questions seeking to obtain information. EMEA staff should follow the procedure laid down in SOP/EMEA/019, Processing & Registration of Enquiries from Third Parties.

Where there is doubt about the provision of information EMEA staff members should seek guidance from their Head of Sector or Unit.

2 *Continuing duty of confidentiality*

Under Article 76 of Council Regulation (EC) No 726/2004 Members of the Management Board, scientific committees and working parties, experts and staff have a life-long duty of confidentiality even after they have ceased their relationship with the EMEA. This covers all information of the kind covered by the obligation of professional secrecy.

Staff members are required to behave with integrity and discretion after leaving the Agency. In addition, in line with Staff Regulations and current commercial practices, the EMEA is entitled to impose restrictions on employment after members of staff leave the EMEA (Article 16 of the Staff Regulations). Staff leaving the EMEA are free to use the skills acquired in the course of their employment at the EMEA so long as such use does not interfere with their obligation of confidentiality. This is, in particular, intended to prevent breaches of confidentiality that would be detrimental to the public interest, interests of the Agency or EU Institutions, Member States, applicants or holders of marketing authorisations.

3 *Public right of access*

There also exists a public right of access to documents that is enforced through the decision of the Management Board on rules on access to documents of the EMEA (EMEA/MB/67083/2004)). These rules set out the procedure for access to documents, the classification of documents as public, EU restricted or EU confidential and the reasons for which access to documents may be denied by the EMEA. Documents classified as EU restricted or EU confidential may not be released to the public.

Once a document or information has been made public, the duty of confidentiality ceases only to the extent of the information released into the public domain.

4 *Cooperation with the European Anti-Fraud Office or Commission Internal Audit Service*

In accordance with European Parliament and Council Regulation (EC) No 1073/1999 concerning investigations conducted by the Office and the Executive Director's decision of 1 June 1999 concerning cooperation with the Office (EDIR/007/1999), staff and experts are required to cooperate fully with the European Anti-Fraud Office. The release of information in response to a request from or in the course of an investigation by the Office shall not constitute a breach of confidentiality.

Information provided to the Commission's Internal Audit Service in the course of its duties shall not constitute a breach of confidentiality.

Annex III – Declaration of interest and confidentiality undertaking

PUBLIC DECLARATION OF INTERESTS AND CONFIDENTIALITY UNDERTAKING OF EMEA COMMITTEES MEMBERS AND EXPERTS

This document consists of two parts, the Public Declaration of Interests and the Confidentiality Undertaking. Both parts should be duly completed. All pages have to be dated and signed. If the document is completed by hand, please ensure that the information required is presented clearly.

PUBLIC DECLARATION OF INTERESTS

I, *(Title)* .... *(Name)* .... *(Surname)* ....

Nationality ________________________________

Organisation/Company ________________________________

Professional address ....

....

Email address ....

do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

(Please tick all boxes, and specify company and product name in case of a declared interest. If necessary, use additional dated and signed sheets)

I have a financial interest in a pharmaceutical company of:	**NO**	**YES**	*Company and Product Name*
• **more than 50,000 Euro or equivalent** (Investment funds excluded)			
• **less than 50,000 Euro or equivalent** (Investment funds excluded)			
I was an employee, consultant, principal investigator, member of a steering committee, an advisory board or an equivalent body *(delete where not applicable)* **for a company in relation to a particular product:**	**NO**	**YES**	*Company and Product Name*
• **currently or in the previous year**			
• **more than a year ago but less than 3 years ago**			
• **more than 3 years ago** [2]			

[1] Information relating to interests older than 5 years need not be provided.

Date and signature: ....

I was an investigator (not principal) for the development of a product:	**NO**	**YES**	*Company and Product Name*
• **currently or in the previous year**			
• **more than a year ago**[1]			
I own a patent on a product			
The organisation I am employed by receives a grant or other funding from a pharmaceutical company (I receive no personal gain)[2]			

Further to the interests declared above, I do hereby declare on my honour that I have/have not *(delete where not applicable)* **any other interests or facts including matters relating to members of your household**[3] **I consider should be made known to the Agency and the public.** *(In case of any other interests or facts, please specify)*

....

....

....

....

....

Should there be any change to the above due to the fact that I acquire additional interests, I shall notify the EMEA and complete a new declaration of interests detailing the changes.

This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any EMEA Activity[4] **in which I participate.**

Date and signature: ....

[1] Information relating to interests older than 3 years need not be provided.
[2] Excluding any fees paid by pharmaceutical industry for assessment work undertaken by National Competent Authorities.
[3] A household member means: spouse, partner and children living at the same address as the declarant. The names of these persons need not be declared.
[4] EMEA Activity encompasses any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the EMEA's Committees, its Working Parties, Expert Groups, or any other such meeting, work as an expert on assessments, and work as an expert on guidance development. Following the assessment of the declared interests the EMEA may limit the input to EMEA activities

Annex IV – Draft contract

SERVICE CONTRACT

CONTRACT NUMBER – EMEA/2006/32/DIR

European Medicines Agency (hereinafter referred to as "EMEA"), which is represented for the purposes of the signature of this contract by Mr. Thomas Lönngren, Executive Director,

of the one part,

and

[full name]
whose registered address is at [official address in full]

(hereinafter referred to as "the Contractor"),

of the other part,

HAVE AGREED

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

Annex I – Tender Specifications (Invitation to Tender No EMEA/2006/32/DIR of [*complete*])

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

Annex III – Deliverables

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

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

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

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

I – SPECIAL CONDITIONS

ARTICLE I.1 - SUBJECT

I.1.1. The subject of the Contract is the external membership of the Agency’s Audit Advisory Committee (the “Services”).

I.1.2. The Contractor shall provide the Services assigned to it in accordance with the Tender Specifications annexed to the Contract (Annex I) and the Deliverables (Annex III).

ARTICLE I.2 - DURATION

I.2.1. The Contract shall become effective on the date on which it is signed by the last contracting party. Provision of the Services shall start from [complete].

I.2.2. Provision of the Services may under no circumstances begin before the date on which the Contract becomes effective.

I.2.3. The duration of the Services shall not exceed the mandate of the Audit Advisory Committee (three years from 1st January, 2006). This period and all other periods specified in the Contract are calculated in calendar days. Provision of the Services shall start from date of entry into force of the Contract. The period of provision of the Services may be extended only with the express written agreement of the parties before such period elapses.

I.2.4. The Contract may be renewed once for a period of provision of Services corresponding with the length of the mandate of the Audit Advisory Committee, with the express written agreement of the parties before the Contract expires, indicating the date on which provision of the Services shall start. Renewal does not imply any modification or deferment of existing obligations.

ARTICLE I.3 – CONTRACT PRICE

I.3.1. The maximum total amount to be paid by EMEA under the Contract shall be [to be completed] exclusive of VAT covering all the Services provided (the "Charges").

I.3.2. It is agreed that the Charges include all other expenditure that may be incurred by the Contractor in performance of this Contract, including travel, subsistence or any other related expenses.

ARTICLE I.4 – PAYMENT PERIODS AND FORMALITIES

Payment of the Charges under the Contract shall be made only if the Contractor has fulfilled all its contractual obligations by the date on which the invoice is correctly submitted. Payment requests may not be made if payments for previous periods have not been executed as a result of default or negligence on the part of the Contractor.

Payments shall be made quarterly in arrears on the basis of an invoice issued by the Contractor and verified by EMEA. Any invoice must give a breakdown of the Charges in accordance with Article I.3.2. Subject to verification by EMEA, payment shall be made within 45 days of receipt of the invoice.

Payment shall be made quarterly in arrears on the basis of invoices submitted by the Contractor. Invoices must detail the Services provided and the number of hours of Services provided.

ARTICLE I.5 – BANK ACCOUNT

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

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

ARTICLE I.6 – NOTICE / ADMINISTRATIVE PROVISIONS

Any notice or other communication relating to the Contract shall be made in writing and shall bear the Contract number. Ordinary mail shall be deemed to have been received by EMEA on the date on which it is registered by the department responsible indicated below. All notices or other communications shall be sent to the following addresses:

EMEA:

EMEA
IQM/Audit
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Contractor:

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

ARTICLE I.7– APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.7.1. The Contract shall be governed and construed in accordance with the laws of England & Wales and the parties hereto agree to submit to the exclusive jurisdiction of the English Courts.

I.7.2. Failing an amicable settlement, the Court of Justice of the European Communities shall have exclusive jurisdiction in any dispute relating to the performance or the interpretation of the Contract.

ARTICLE I.8 – TERMINATION BY EITHER CONTRACTING PARTY

Either party may, of its own volition and without being required to pay compensation, terminate the Contract by serving three months' formal prior notice. Should EMEA terminate the Contract, the Contractor shall only be entitled to payment corresponding to part-performance of the Services before the date termination is notified to become effective ("Termination Date"). On receipt of such notice from EMEA, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce its commitment in relation to EMEA. It shall draw up any documents required by the Contract and its Annexes for the Services provided up to the Termination Date on which termination takes effect.

ARTICLE I.9 – OTHER SPECIAL CONDITIONS

The Contractor hereby confirms that he/she will allocate sufficient time to their task to contribute actively in meetings and the ongoing work of the Committee. He/she agrees to attend all of the Committee's meetings, unless cases of "force majeure" as defined in Article II.12 of this Contract, which must be communicated to the EMEA at least two weeks before the meeting date. Unforeseen circumstances must be communicated to EMEA as soon as they happen or as soon as it is possible.

II – GENERAL CONDITIONS

ARTICLE II.1 – PERFORMANCE OF THE CONTRACT

II.1.1. The Contractor shall perform the Services to the highest professional standards. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on it, notably, but not limited to, those resulting from employment, tax and social legislation.

II.1.2. The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for performance of the Services under the laws and regulations in force at the place where the Services are to be provided.

II.1.3. N/A

II.1.4. N/A

II.1.5. The Contractor shall neither hold itself out as representing EMEA nor behave in any way that would give such an impression. The Contractor shall inform third parties that it does not belong to the European public service.

II.1.6. The Contractor's appointment is on personal basis and no work can be subcontracted to others, including the Contractor's staff.

II.1.7. N/A

II.1.8. Should any unforeseen event, action or omission directly or indirectly hamper execution of the Services, either partially or totally, the Contractor shall immediately and on its own initiative record it and report it to EMEA. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken by the Contractor to ensure full compliance with its obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.

II.1.9. Should the Contractor fail to perform its obligations under the Contract in accordance with the provisions laid down therein, EMEA may - without prejudice to its right to terminate the Contract - reduce or recover payments in proportion to the scale of the failure. In addition, EMEA may impose penalties or liquidated damages provided for in Article II.16.

ARTICLE II.2 – LIABILITY

II.2.1. EMEA shall not be liable for any claim, loss, cost or expense sustained by the Contractor in performance of the Contract except in the event of wilful misconduct or gross negligence on the part of EMEA.

II.2.2. The Contractor shall be liable for any claim, loss, cost or expense sustained by EMEA but caused by the performance of the Contract, including that arising in the event of subcontracting under Article II.13. EMEA shall not be liable for any act or default on the part of the Contractor in performance of the Contract.

II.2.3. The Contractor shall indemnify and hold EMEA harmless and provide compensation in the event of any action, claim or proceeding brought against EMEA by a third party caused by the Contractor in performance of the Contract.

II.2.4. In the event of any action brought by a third party against EMEA in connection with performance of the Contract, the Contractor shall assist EMEA. Expenditure incurred by the Contractor to this end may be borne by EMEA.

II.2.5. The Contractor shall take out and maintain for the duration of the Contract insurance against all normal business risks and damage relating to performance of the Contract including but not limited to Employer's Liability Insurance (if applicable) and Public Liability Insurance, both to a minimum cover of £5,000,000.00 or the equivalent in Euro. If required by the relevant applicable legislation, the Contractor shall take out supplementary insurance as reasonably required in accordance with reasonably prudent practices in its industry. A copy of all the relevant insurance contracts shall be sent to EMEA should it so request.

ARTICLE II.3 - CONFLICT OF INTERESTS

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

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

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

II.3.3. The Contractor declares:

- that it has not made and will not make any offer or agreement with any third party of any type whatsoever from which an advantage can be derived under the Contract,
- that it has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any third party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to performance of the Contract.

ARTICLE II.4 – PAYMENTS

II.4.1. If any reports to be submitted by the Contractor are a condition for payment, on receipt EMEA shall have 60 calendar days for approval of such reports.

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

ARTICLE II.5 – GENERAL PROVISIONS CONCERNING PAYMENTS

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

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

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

II.5.3. In the event of late payment caused other than by the Contractor's default the Contractor may claim interest within two months of receiving the payment. Interest shall be calculated at the rate applied by the European Central Bank to its most recent main refinancing operations (*"the reference rate"*) plus seven percentage points (*"the margin"*). The reference rate in force on the first day of the month in which the payment is due shall apply. Such interest rate is published in the C series of the Official Journal of the European Union. Interest shall be payable for the period elapsing from the calendar day following expiry of the time limit for payment up to the day of payment. Suspension of payment by EMEA may not be deemed to constitute late payment.

ARTICLE II.6 – RECOVERY

II.6.1. If total payments made exceed the amount actually due under the Contract or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse the appropriate amount on receipt of the debit note, in the manner and within the time limits set by EMEA.

II.6.2. In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.

II.6.3. EMEA may, after informing the Contractor, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Contractor also has a claim on the Communities that is certain, of a fixed amount and due. EMEA may also claim against any guarantee, where provided for.

ARTICLE II.7 – NOT APPLICABLE

ARTICLE II.8 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

II.8.1. Any copyright, trademarks, tradenames, designs or patents (whether registered or unregistered) including all other intellectual or industrial property rights (the "Intellectual Property Rights"), arising, or created by the Contractor, in the performance of the Contract, shall be owned solely by EMEA, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation.

II.8.2. Where Intellectual Property Rights exist prior to the Contract being entered into and are utilised in the provision of, and ongoing benefit of, the Services the Contractor shall, or shall procure that any third party owner of said Intellectual Property Rights shall, grant to EMEA a perpetual, royalty free licence in connection therewith.

II.8.3. The Contractor shall execute any documents and do all things necessary to vest the Intellectual Property Rights, referred to in Article II.8.1 above, in the ownership of EMEA as may be requested by EMEA from time to time.

II.8.4. The Contractor represents and warrants that the Intellectual Property Rights arising, or utilised, in accordance with Articles II.8.1-2 are or shall be original and will not infringe any

Intellectual Property Rights owned by any third party (including, but without limitation to, all moral rights).

ARTICLE II.9 – CONFIDENTIALITY

II.9.1. In this Article, “Information” shall include any information intentionally or unintentionally provided directly or indirectly by either EMEA or the Contractor to the other in oral or documentary form or by way of electronically accessible media or other tangible form or by demonstrations and whether created or arising in connection with the Services or existing before, on or after the date of the Contract.

II.9.2. In this Article, “Confidential Information” shall mean:

(a) in respect of Information provided in documentary or by way of a presentation or in other tangible form, Information which at the time of provision is marked or otherwise designated to show expressly or is created or arises as a consequence of the provision of the Services or by necessary implication that it is imparted in confidence; and

(b) in respect of Information that is imparted orally, any information that EMEA or its representatives informed at the time of disclosure was imparted in confidence; and

(c) in respect of Confidential Information imparted orally, any note or record of the disclosure; and

(d) any copy of any of the foregoing; and

(e) the fact that Services are being provided hereunder.

II.9.3. The Contractor undertakes to treat in the strictest confidence and not make use of or divulge or disclose to any third parties any Confidential Information. The Contractor shall continue to be bound by this undertaking after the termination or expiry of this Contract.

II.9.4. The Contractor shall take due care that the information received from EMEA by mail, e-mail, fax or any other means is properly stored to ensure that it is not available to any external party.

EMEA will provide the Contractor with an e-mail account (Eudralink) for the secure transmission of the information, but it is the Contractor’s responsibility to have proper arrangements in place that ensure confidentiality once this information reaches his/her offices. EMEA may request a description of the arrangements in place.

The Contractor must, by the Termination Date of the Contract, return all paper files and delete all electronic files containing confidential information related to the EMEA, the Services or any other issue related to this Contract.

The Contractor shall remain liable for the disclosure of confidential information when it shows that proper due care was not taken to ensure the custody of such information. Burden of proof shall lie with the Contractor.

ARTICLE II.10 - USE, DISTRIBUTION AND PUBLICATION OF INFORMATION

II.10.1. The Contractor shall authorise EMEA to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, any data contained in or relating to the Contract, in particular the identity of the Contractor, the subject matter, the duration, the amount paid and any Confidential Information (as defined in Article II.9 above).

II.10.2. Unless otherwise provided by the Special Conditions, EMEA shall not be required to distribute or publish documents or information supplied in performance of the Contract. If it decides not to publish the Confidential Information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from EMEA.

II.10.3. Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from EMEA and shall mention the amount paid by EMEA. It shall state that the opinions expressed are those of the Contractor only and do not represent EMEA's official position.

II.10.4. The use of Confidential Information obtained by the Contractor in the course of the Contract for purposes other than its performance shall be forbidden, unless EMEA has specifically given prior written authorisation to the contrary.

ARTICLE II. 11 – TAXATION

II.11.1. The Contractor shall have sole responsibility for compliance with the tax laws which apply to it. Failure to comply shall render the relevant invoices invalid.

II.11.2. The Contractor recognises that EMEA is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities.

II.11.3. The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and Services required for performance of the Contract are exempt from taxes and duties, including VAT (if applicable).

II.11.4. Invoices presented by the Contractor shall indicate its place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

ARTICLE II.12 – FORCE MAJEURE

II.12.1. Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties including acts of terrorism which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.

II.12.2. Without prejudice to the provisions of Article II.1.9, if either party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgment of receipt or equivalent, stating the nature, likely duration and foreseeable effects.

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

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

ARTICLE II.13 – SUBCONTRACTING

The Contractor shall not subcontract the performance of the Services nor cause the Contract to be performed in fact by third parties.

ARTICLE II.14 – ASSIGNMENT

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

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

ARTICLE II.15 – TERMINATION BY EMEA

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

(a) where the Contractor is unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986, is being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations applicable to the Contractor;

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

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

(d) where EMEA has reasonable grounds to suspect the Contractor of fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to EMEA's financial and/or reputational interests;

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

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

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

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

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

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

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

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

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

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

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

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

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

II.15.6. Consequences of termination:

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

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

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

ARTICLE II.16 – LIQUIDATED DAMAGES

Should the Contractor fail to perform its obligations under the Contract within the time limits set by the Contract, then, without prejudice to the Contractor's actual or potential liability incurred in relation to the Contract or to EMEA's right to terminate the Contract, EMEA may decide to impose liquidated damages of 0.2% of the amount specified in Article I.3.1 per calendar day of delay. The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on its part or of written withdrawal by EMEA within thirty days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. EMEA and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

ARTICLE II.17 – ACCESS, INSPECTION AND AUDITS

II.17.1 The Contractor, during the currency of the Contract shall gather, compile, correlate, collect and otherwise maintain all relevant accounts, records, books and other information in documentary form or on easily accessible electronic media (“Records”), arising in connection with the performance of the Contract.

II.17.2. In accordance with EMEA’s Financial Regulation, the European Court of Auditors shall be entitled upon reasonable notice to access, inspect and audit the Records held by the Contractor in connection with the performance of the Contract up to five years after the last payment is made to the Contractor by EMEA.

II.17.3. EMEA or an outside body of its choice shall have the same rights as the European Court of Auditors for the purpose of access, inspection and audit of the Records in accordance with Article II.17.2 above.

II.17.4. In addition, the Contractor acknowledges that the European Anti Fraud Office may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 and Parliament and Council Regulation (EC) No 1073/1999 and agrees to submit thereto.

ARTICLE 11.18 – CANCELLATION OF SERVICES

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

ARTICLE II.19 – WHOLE AGREEMENT AMENDMENTS

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

ARTICLE II.20 – SUSPENSION OF THE CONTRACT

Without prejudice to EMEA's right to terminate the Contract, EMEA may at any time and for any reason suspend provision of the Services under the Contract or any part thereof. Suspension shall take effect on the day the Contractor receives notification by registered letter with acknowledgment of receipt or equivalent, or at a later date where the notification so provides. EMEA may at any time following suspension give notice to the Contractor to resume the Services suspended. The Contractor shall not be entitled to claim compensation on account of suspension of the Contract or of part thereof.

SIGNATURES

For the Contractor, [*Company name*/forename/surname/title]	For EMEA, [forename/surname/title]
signature[s]: ________________________	signature[s]:_____________________
Done at [place], [date] In duplicate in English.	Done at London, [date]

Annex V – Exclusion criteria statement and detail of supporting documentation required

Tenderers must:

- Answer the following questions by indicating yes or no in each case. Any tenderer answering yes to any of these questions shall be excluded automatically from participation in the tender.

- Provide the supporting documents defined below after the questions in support of these answers (either Proof A, B or C or in some cases "Not Applicable").

- Provide the signed and dated declaration regarding conflict of interest and serious misrepresentation detailed on the next page.

Question no.	Question	Answer Yes/No	Proof required (see below)
1	Is the tenderer insolvent (or the subject of bankruptcy proceedings if an individual) or being wound up?	Yes/No	Proof A or C required.
2	Is the tenderer having its affairs administered by the courts?	Yes/No	Proof A or C required.
3	Has the tenderer entered into an arrangement with creditors?	Yes/No	Proof A or C required.
4	Has the tenderer suspended business activities?	Yes/No	Proof A or C required.
5	Is the tenderer the subject of proceedings concerning any such matters referred to in 2.1, 2.2, 2.3 or 2.4 above or in any analogous situation arising from a similar procedure provided for in national legislation or regulations?	Yes/No	Proof A or C required.
6	Has the tenderer been convicted of any offence (if an individual) or judgment been made against it concerning its professional conduct by a judgment which has the force of res judicata?	Yes/No	Proof A or C required.
7	Has the tenderer been guilty of grave professional misconduct?	Yes/No	Not Applicable
8	Has the tenderer failed to fulfil its obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed?	Yes/No	Proof B or C required.
9	Has the tenderer been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a	Yes/No	Proof A or C required.

	criminal organisation or any other illegal activity detrimental to the European Community's financial interests?		
10	Following any other procurement procedure or grant award procedure financed by the European Community budget, has the tenderer been declared to be in serious breach of contract for failure to comply with their contractual obligation?	Yes/No	Not Applicable

<u>Supporting documentation to be provided in support of above responses:</u>

In support of the above responses, please provide the following documents:

A. Proof regarding situations mentioned in points 1, 2, 3, 4, 5, 6 and 9 in the form of a recent extract from the judicial record, or failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that these requirements are satisfied. The extract(s) or equivalent documentation must be the most reasonably available.

B. EMEA will accept a recent certificate issued by the competent authority of the country concerned as satisfactory evidence that the tenderer is not in the situation mentioned in point 8 above. The certificate must be dated less than four months before the final date for submission of this tender.

C. Where no such certificates or documents are issued in the country concerned, they may be replaced by a sworn or a solemn statement made by the tenderer before a judicial or administrative authority, a notary or a qualified professional body in the country of origin or provenance.

Please note that supporting documents provided must relate to legal persons and/or natural persons including, where considered necessary by EMEA, company directors or any person with powers of representation, decision-making or control in relation to the candidate.

<u>Tenderers should also sign and date the declaration below. Signature should be by either a company director or any person with powers of representation or control in relation to the candidate as follows</u>:

- I hereby confirm that [insert name] does not have any conflict of interest in connection with the contract arising from economic interests, political or national affinities, family or emotional ties, or any other relevant connection or shared interest;

- I confirm that EMEA will be informed, without delay, of any situation constituting a conflict of interest or which could give rise to a conflict of interest;

- I confirm that no offer of any type whatsoever from which an advantage can be derived under the contract has been or will be made;

- I confirm that [insert name] has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to the award of the contract.

- I confirm that [insert name] is not guilty of any serious misrepresentation, either knowingly or negligently, in supplying any information required by EMEA.

- I acknowledge that EMEA reserves the right to check the responses to the above information.

Signed:
Print name of tenderer

Date:

Annex VI – Summary checklist of documents which tenderers must submit

1. Cover letter enclosing the tender signed and dated by the Tenderer.

2. Tender in three copies (one original, clearly marked as original, and two copies), containing the following elements:

   2.1. Information sheet on the tenderer (as detailed in point 16 above).

   2.2. Completed questionnaire in Annex V relating to Exclusion Criteria AND supporting documentation together with declaration regarding conflict of interests.

   2.3. Documentation requested to enable assessment of Selection Criteria (points 13 and 14 above).

      2.3.1. Sworn signed declaration stating the total annual turnover for study, advisory and audit works finalised in the past 3 years. When possible, the declaration must be accompanied by relevant official documents (such as tax declarations)

      2.3.2. Proof of authorisation to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

      2.3.3. Copy of university degree or equivalent national qualification entitling the tenderer to undertake post-graduate studies.

      2.3.4. Proof of the length of professional experience. Proof of professional experience must state both the start and the end dates and the duties performed. Only experience acquired after obtaining a university degree or equivalent national qualification may be taken into account.

   2.4. Documentation requested to enable assessment of Award Criteria (point 15 above).

      2.4.1. Curriculum Vitae, clearly showing the qualifications and professional experience.

      2.4.2. Proof of experience with Audit Committees, when applicable

      2.4.3. Separate sheet describing previous experience relevant to the requirements of membership of the AAC (maximum 400 words). For details of what it's considered as relevant experience, please refer to the areas of knowledge described in points 3.1.3, 3.1.4. and 3.1.5 of this document.

      2.4.4. Separate sheet describing how the knowledge of the institutions of the European Union, its main policies and procedures has been acquired (maximum 200 words).

      2.4.5. Details of any vocational/professional qualifications or certifications in the fields described in point 3 of this tender. Certifications awarded by national bodies (i.e., certified accountants according to their Member States requirements) should be complemented with a brief description of the requirements at national level (years of professional experience, university degrees…). Please, include photocopies of the certifications awarded; originals will be requested if the tenderer is selected prior to the signature of the contract.

2.4.6. Details of registration with a professional organisation, relevant to the duties described in point 3 of this tender. Please, provide proof of current registration (letter dated not more than 3 months ago, proof of payment of membership fees, …)

2.4.7. Proven knowledge of English at sufficient level, documented either through relevant diplomas, educational background or professional experience. Please, provide a brief explanation, when necessary.

2.4.8. Any other document/proof that the tenderer may deem appropriate to support any of the award criteria detailed in point 15 above. References must be accompanied by a signed statement detailed in Annex VII. Please, provide details and explanations.

2.4.9. **<u>To be submitted in a separate binder or folder, which must be clearly labelled</u>**, a detailed financial tender with all-inclusive daily rate, and exclusive of VAT, signed by an authorised representative of the tenderer.

2.5. A statement to confirm that information provided in response to this tender is accurate and complete as at the date of submission and acknowledgement that the provision of false information in response to this tender could result in the tenderer being excluded from future tenders for contracts with EMEA.

2.6. An undertaking to inform EMEA promptly following any matter that would alter or add to any of the information given in response to this tender.

* * * * * * *

Annex VII – Declaration of independence by referee

I *(full name)* ____, the signatory, declare that I have provided Mr/Mrs *(name of tenderer)* ______________________________________ with the following documents:

- ☐ Reference letter
- ☐ Work certificate
- ☐ Other/s *(please, specify)* _____________________________________

I declare that the information given in the above-mentioned documents is true.

I declare that I do not have any family, financial or any other type of relationship that may compromise my independence and objectivity with regards to the tenderer.

I hereby authorise the European Medicines Agency to contact me to verify any of the aspects of these documents and its contents.

Signed

Name

Position

Company

Date