



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 February 2013

EMA/988338/2011 (Rev.1)

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Application Form¹: Call for Expression of Interest

Ref. No. EMA/2012/08/CN ("Drug Safety Studies")

1. APPLICANT ²			
Name of Applicant			
Name of responsible person		Title:	Please select
Address 1			
Address 2			
City			
Postcode			
Country			
Telephone	+		
Alternative Telephone	+		
Fax	+		
E-mail			
Website / Homepage			
Legal Status			
VAT Number (if applicable)			
<i>Contact details for any other person(s) that should be copied in all correspondence relating to this application:</i>			
Name			
E-mail			

¹ Complete the form on screen, then print and sign.

² Incomplete applications will not be taken into account.



2. AREAS OF INTEREST ³ [See item 3. of notice EMA/2012/08/CN]		
Lot No.	Yes	No
1-Comparative reviews of drug utilisation patterns	☒	☐
2-Observational studies (electronic healthcare and other databases)	☒	☐
3-Observational safety or benefit:risk studies (primary data collection)	☒	☐
4-Systematic reviews or meta-analysis	☒	☐

3. ANNEXES (EXCLUSION and SELECTION Criteria) [Please provide original documents wherever possible]		
Item:	Please check	Annex no.
Declaration upon honour – Exclusion & Conflict of Interest⁴	☐	
- Proof (indicate whether A, B or C)	☐	
Proof of enrolment on the professional register or similar, in accordance with provisions in force in the candidate's country of residence	☐	
Proof of economic and financial capacity		
(a) Most recent audited accounts (3 years)	☐	
(b) Statement of turnover, profit & loss and cash flow position	☐	
(c) Details of professional indemnity insurance	☐	
(d) Other	☐	
Proof of technical and professional capacity		
(a) Curricula vitae	☐	
(b) List of main observational drug safety studies (indicate lot no.)	☐	
(c) List of recent publications	☐	
(d) Description of guaranteed and continued access to data sources (if applicable)	☐	
(e) Quality assurance accreditations and/or policy incl. description of facilities	☐	
Others:	☐	

Done at _____, on ____ / ____ / ____

Signature: _____

Print name and title of signatory: _____

Representing [insert name of Applicant]: _____

³ Please indicate which lots you are applying to be shortlisted for and which ones you are not interested in

⁴ Declaration upon honour in Annex I

Annex I. DECLARATION UPON HONOUR

It is MANDATORY to complete all parts highlighted in grey.

The undersigned *(insert name of the signatory of this form)*:

☐ representing the following person: *(only if the economic operator is a legal person)*

Full official name:

Official legal form:

Full official address:

VAT registration number:

OR

☐ in [his][her] own name *(only if the economic operator is a natural person)*

➤ declares that the above-mentioned legal person⁵ is not in one of the following situations:

- a) is bankrupt or 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;
- b) has been convicted of an offence concerning professional conduct by a judgement of a competent authority of a Member State which has the force of *res judicata*;
- c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;
- d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;
- e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organization, money laundering or any other illegal activity, where such activity is detrimental to the European Union's financial interests;
- f) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of

⁵ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

participation in a procurement procedure or failing to supply this information, or having been declare to be in serious breach of its obligations under contracts covered by the European Union's budget.

- declares that the natural persons with power of representation, decision-making or control⁶ over the above-mentioned legal entity are not in the situations referred to in b) and e) above;
- declares that the above-mentioned legal person ⁷:
- g) has no conflict of interest in connection with the application; a conflict of interest could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) 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, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure;
- acknowledges that the above-mentioned legal person ⁸ may be subject to administrative and financial penalties⁹ if any of the declarations or information provided prove to be false.
- confirms that the required supporting documentation, as indicated below, is provided and attached to this signed declaration.

⁶ This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

⁷ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁸ In case of NATURAL person, replace "the above-mentioned legal person" by "he or she"

⁹ As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

MANDATORY SUPPORTING DOCUMENTATION TO BE PROVIDED IN SUPPORT OF ABOVE RESPONSES:

PROOF	MANDATORY DOCUMENTATION REQUIRED
A	For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the applicant is a legal person and the national legislation of the country in which the applicant is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the applicant.
B	For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the applicant is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.
C	For any of the situations (a), (b), (d) or (e), where any document described in the two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.
D	If the applicant is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

If an Applicant has any doubt about the mandatory documentation required, it is strongly recommended that the appointed person at the Agency is contacted for clarification since failure to provide the correct documents may lead to elimination from the procedure.

Date:

Signature of authorized
representative:

(Print name):

Position in Company:

Representing (name of applicant):

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Applicants are reminded that the Agency is unable to accept electronic signatures and will not accept photocopies of the completed declaration.