EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 February 2015
EMA/60018/2015
Procedure Management and Business Support Division

Call for expressions of interest, from terminology maintenance organisations, software vendors, service providers and developers of medicinal product dictionaries/databases, for membership in a Task Force for the implementation of international standards on identification of medicinal products in the EU (i.e. EU ISO IDMP Task Force)

Background

With this call the European Medicines Agency is looking for representatives nominated by terminology maintenance organisations, software vendors and developers of medicinal product dictionaries/databases in the EU ISO IDMP Task Force.

In December 2010, new pharmacovigilance legislation (Regulation (EU) No 1235/2010 amending Regulation No 726/2004 and Directive 2010/84/EU amending Directive 2001/83/EC) was adopted by the European Parliament and European Council. Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 require the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. Specific reference is made to the ISO Identification of Medicinal Product (IDMP) standards that were finalised in 2012 and the implementation guides, which are currently under development at international level.

The Agency, in consultation with the EU regulatory network, is currently developing an EMA roadmap to implement Substance, Product, Organisation and Referential (SPOR) master data management services, which will also support the implementation of the ISO IDMP standards.

The Agency and the EU Regulatory Network are pursuing an open dialogue with industry to discuss aspects of the implementation of the ISO IDMP standards in Europe by establishing an ISO IDMP Task Force, which would include participation from terminology organisations, software vendors, service providers and developers of medicinal product dictionaries/databases.

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This forum will be responsible for advising on aspects related to planning, development, implementation and maintenance of the ISO IDMP Standards in EU in line with the requirements defined at international level and based on the agreed EU Implementation principles.

Composition of the EU ISO IDMP Task Force

The EU ISO IDMP Task Force will include representatives from:

- National Competent Authorities (NCAs) from within existing working groups;
- pharmaceutical industry as nominated by the European pharmaceutical industries associations;
- software vendors, service providers, developers of medicinal product dictionaries/databases, nominated by Industry Associations, or expressing their interest to participate directly via this call;
- organisations dealing with provision and maintenance of terminologies supporting the electronic exchange of information related to medicinal product and substance information expressing their interest to participate directly via this call.

In order to ensure a balanced and broad representation, the group membership would be limited to around 60 members. The Agency would consider organising teleconferences in order to accommodate a larger number of participants.

Workload and allowances

The EU ISO IDMP Task Force will meet four times in 2015 at the Agency and may also convene ad-hoc meetings via conference calls/webinars.

All participants will bear their own costs and expenses related to their participation in the EU ISO IDMP Task Force, with the exception of representatives of the NCAs whose costs and expenses will be reimbursed in accordance with the Agency's “Rules for reimbursement of expenses for delegates and experts attending meetings” (EMA/MB/270654/2014).

Assessment criteria

The expressions of interest of representatives nominated by software vendors, service providers, developers of medicinal product dictionaries/databases and terminology maintenance organisations will be evaluated based on the following criteria:

- individuals have the relevant and proven expertise related to:
  - medicinal product for human use and substance and other terminology data management,
  - provision of solutions to support the EU regulatory requirements for the electronic submission of information on medicinal products for human use,
  - EU regulatory requirements for medicinal product (for human use) lifecycle management covering diverse regulatory processes (e.g. clinical trials, application submission, pharmacovigilance and post-authorisation activities);
- knowledge and understanding of the ISO IDMP standards, other pertinent EU standards and the international standardisation processes;

- individuals working within renowned organisations dealing with terminologies that enable health professionals, industry and regulators to collect, codify, access information on medicinal product and/or substance information;
- individuals working within internationally recognised services providers and maintenance organisations contributing to public health, supporting public administration and cooperating with pharmaceutical industry;
- individuals being members of ISO IDMP-related working groups, task forces or other standard development organisations.

Due to the fact that the working language of the EU ISO IDMP Task Force will be English and there will be no translation services available, prospective members of the Task Force should have good working knowledge of English.

Application procedure and closing date

At the time of the application, the interested person must provide the following documents:

1. a letter of motivation (signed);
2. curriculum vitae;
3. any other document supporting the above assessment criteria.

The letter of motivation and CV should be provided in English; however, the relevant supporting documentation will be also accepted in one of the official languages of the European Union.

The complete application must be sent not later than 6 March 2015 to the following email address: art57@ema.europa.eu. The subject of the email should contain the phrase "*EU ISO IDMP Task Force: expression of interest*".

Appointment process

The Agency will review the applications and, following assessment, will inform the successful candidates by 31 March 2015.

Protection of personal data

The Agency will ensure that candidates' personal data are processed as required by Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1). This applies in particular to the confidentiality and security of such data.

For more detailed information on the scope, purposes and means of the processing of their personal data in the context of this Call for expression of interest, candidates are invited to consult the EMA Privacy Policy.