

Delft, 9 September 2008

Joint CEN/TC 251 & ISO/TC 215 & HL7 Project "Pharmacovigilance & Identification of medicinal products"

OPEN CALL FOR PROJECT TEAM MEMBER Deadline for Replies: 10 October 2008

The CEN Project Team is seeking a new member to participate in the joint CEN/TC 251, ISO/TC 215 and HL7 project "Pharmacovigilance & Identification of medicinal products" (resorting under ISO/TC 215/WG 6 Pharmacy and medication).

The candidate is requested to have excellent knowledge of English language (in writing), thorough knowledge of ISO/CEN drafting rules and medicines terminology. The candidate is requested to show the ability to achieve homogeneous set of 7 documents which are under development to become parallel international and European standards, preferably by drafting a general applicable model for the standards which are under development identified as part of "Identification of medicinal products". The candidate is requested to be in close communication with the task group who is working on the work items and in particular the designated editors of the work items.

The current Project Team has been appointed in 2006 in accordance with the CEN rules (following the FPA Guidelines). Due to a vacancy, we are seeking a new member for the Project Team. It has been estimated that the new member will need 40 days maximum in total to achieve his tasks for all work items. Most of the man-days will be spent before the end of 2009.

The European Commission has issued in 2006 a contract to CEN, European Standardization Organization, "to review six message specifications that either have been, or are in the process of being defined - in the context of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) - and to prepare them for formal adoption as European standards in accordance with the criteria set out in Directive 98/34/EC of the European Parliament and of the Council ("The Directive)". The message specifications in question are:

1. The electronic Common Technical Document;
 - a. The scope of the ICH specification for general purposes
 - b. The EU Module 1 for regional specificities**> The development of this work has been discontinued**
2. The Product Information Management (PIM) Data Exchange Standard;
> The development of this work has been discontinued
3. The latest version of the E2B message for Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs);
4. The Medicinal Product Identifier;
5. The Medicinal Vocabulary Message;
6. The Application Form.
> The development of this work has been discontinued

In 2008, three of the six deliverables have been discontinued. The deliverables 3, 4 and 5 are currently under development through seven work items:

- 1) prEN ISO 27953 Health informatics – Pharmacovigilance – Structure and data elements for individual case safety reports
- 2) prEN ISO 11595 Health informatics – Pharmacovigilance – Test names and units for reporting laboratory results
- 3) prEN ISO 11615 Health informatics – Identification of Medicinal Products – Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries

- 4) prEN ISO 11616 Health informatics – Identification of Medicinal Products – Pharmaceutical Product Identifiers
- 5) prEN ISO 11238 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Ingredients
- 6) prEN ISO 11239 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration
- 7) prEN ISO 11240 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Units of Measurement

The Terms of References (ToR) with a detailed description of what is expected from the Project Team is attached in Annex I (**updates have been indicated in bold**). For the Project Team a funding is available of € 650 per Man-day (including VAT) via a specific Grant Agreement between CEN, the European Commission and European Free Trade Association (EFTA). In Annex II, you will find the rules for the setting up and functioning of a Technical Committee Project Team in CEN. In line with the CEN general rules on the selection and appointment of the Project Team a panel has been installed.

Members of the panel are:

1. Kees Molenaar, CEN/TC 251 Chair,
2. Ian Shepherd, ISO/TC 215/WG 6 convenor,
3. Anna von Groote, CEN Central Secretariat,
4. A representative of the European Commission,
5. Shirin Golyardi, CEN/TC 251 secretary (on behalf of NEN).

The outcome of the selection process will be communicated as soon as possible.

The reimbursement rate for accepted experts is 650 €/person/day (including VAT).

Payments to Project Team experts are dependent on NEN having received the corresponding payments by CEN. Applicants need to realise that the delay before NEN being in a position to issue the final payment (of 35%) may be in the order of several months.

Interested candidate experts are kindly requested to send their nominations by 10 October 2008, to Shirin Golyardi (shirin.golyardi@nen.nl). Please use the application form in Annex III along with a short Curriculum Vitae (preferred method is by email).

Yours sincerely,

Shirin Golyardi.
CEN/TC 251 secretary

Annex I

Original Terms of Reference for a Project Team on “ICH messages” (updates indicated in bold)

The Project Team will report to CEN/TC 251 Health informatics

1. Objective

The objective of this project is to review six message specifications that either have been, or are in the process of being defined and to prepare them for formal adoption as European standards in accordance with the criteria set out in Directive 98/34/EC of the European Parliament and of the Council ("The Directive"). The specifications in question are:

1. The electronic Common Technical Document;
 - a. The scope of the ICH specification for general purposes
 - b. The EU Module 1 for regional specificities
2. The Product Information Management (PIM) Data Exchange Standard;
3. The latest version of the E2B message for Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs);
4. The Medicinal Product Identifier;
5. The Medicinal Vocabulary Message;
6. The Application Form.

The development of deliverables 1, 2 and 6 has been discontinued.

These specifications have been developed either in the context of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)¹ or for adoption by the Notice to Applicants Working Group². The specifications, while generally accepted in the context of the regulation of pharmaceuticals in Europe, have not been developed in accordance with the criteria in the Directive. The results of the project – European Standards – will contribute to acceptance of formal standards in this arena in Europe, which will also be proposed internationally through ISO.

2. Rationale

The rationale is discussed in respect of each of the specifications separately.

Deliverable 3: The E2B message for Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs)

This ICH guideline standardises the data elements for the transmission of ICSRs by identifying and defining the data elements for the transmission of all types of ICSRs, regardless of source and destination. This includes case safety reports for both pre- and post-approval periods and covers both adverse drug reaction and adverse event (AE) reports. The guideline states that because of national and international agreements, rules, and regulations, ICSR of adverse drug reactions and AE should be transmitted:

- From identified reporting sources to regulatory authorities and pharmaceutical companies
- Between regulatory authorities
- Between pharmaceutical companies and regulatory authorities
- Within authorities or pharmaceutical companies
- From clinical investigators, via the sponsor, to ethics committees
- From authorities to the WHO Collaborating Centre for International Drug Monitoring.

This information is important to all regulators to assist in detecting signals, and hence a standard means of transmitting the information is essential to enable efficient use of the information and the maximisation of the signal detection effort through the analysis of larger populations of data.

¹ For further information on ICH, see www.ich.org

² The Notice to Applicants Working Group (NtAWG) is responsible for the regulatory guidelines that define the procedures for marketing authorisation and the presentation and content of the dossier as part of the rules governing medicinal products for human use in the European Community. It has representatives of all European competent authorities and is chaired by the European Commission.

Deliverable 4: The Medicinal Product Identifier

The Medicinal Product Identifier is currently contained in a draft ICH guideline – “Data Elements and Standards for Drug Dictionaries”. It has been established to standardise key elements of the information relating to a medicinal product and thus to facilitate the intensive information exchange during the development, evaluation, approval and post-authorization phases of the lifecycle of a medicinal product. It is expected to underpin the exchange of information between regulators and pharmaceutical industry by:

Enabling the exchange medicinal product information between regulators and industry in a structured and efficient way;

Facilitating the assurance of data consistency and hence the evaluation and comparison of medicinal product-related information across the ICH regions through harmonised definitions of terminologies and data sets, particularly in the area of pharmacovigilance;

Assisting in the reduction in the administrative burden and duplication of efforts requiring substantial human and financial resources for the pharmaceutical industry to comply with, and handle different regional requirements; and

Helping to assure consistency in the use of terminology in the health care community.

Deliverable 5: The Controlled Vocabulary Message

Use of the Controlled Vocabulary Message is intrinsic to the success of the Medicinal Product Identifier, and its use is also addressed in the draft ICH Guideline “Data Elements and Standards for Drug Dictionaries”. Due to different regulatory standard terminologies being in place in the ICH regions and observer countries, it is difficult to exchange information at the international level. Controlled vocabularies are being established at ICH, and a standard message format to ensure that these terminologies are exchanged according to an agreed structure is required. Formal standards will further assist in the adoption of the structure, and help to assure international interoperability. This chapter should clearly describe the context of the proposal. In particular, it should explain the need (from industry or consumer side) for this initiative and whether the proposal is linked to (a) previous/other eSAP proposal(s), to R&D projects or activities in other bodies. If this is the case, some information and the reference concerning these links should be given. Reference documents should be indicated. It should be made clear whether the proposal has the dimension or an “added value” to improve the situation described under chapter 1.

3. Policy relevance and Market impact

This proposal is made in response to Action 18 of the ICT Standardization Work Programme 2006. In the context of increasing globalisation of the development of medicinal products, the importance of international agreement on standards for the exchange of information is increasing. Such standards enable efficiencies to be achieved by the research-based pharmaceutical industry in the submission of information in support of applications for marketing authorisations, and also allow for improved quality of analysis in support of pharmacovigilance activities. General recognition of the importance of exchange standards in this arena has led to specifications for messages to achieve the same results being developed in parallel by different organisations internationally.

4. Working method/approach

The development of the six European and International Standards fall under the responsibility of CEN/TC 251 (specifically WG I). CEN will pursue cooperation with ISO/TC 215/WG 6 to develop concurrently International and European standards using the Vienna Agreement. The work items fit within the scope of ISO/TC 215/WG 6 ‘pharmacy and medicines business’ in which experts of European member states and other countries participate. The division of work between experts and over work items may vary.

5. Performance indicators

The joint effort of CEN and ISO will ensure that relevant experts are involved in this project.

6. Timetable and Deliverables

The original timetable has been altered since the beginning of the project.

The following time frames have been estimated for the rest of the project:

The deliverables should be finished by the first quarter of 2010 (as the contract with the European Commission states). The current estimation is to have the Committee Draft Ballot (3 months) by the end of 2008, the parallel Draft International Standard (DIS) / Enquiry ballot of 5

months in 2009 and the parallel Final Draft International Standard (FDIS) and Final Vote (FV) Ballot of 2 months end of 2009.

7. Project Team man day allocation

The original budget for the Project Team was a maximum total of 360 days at € 650 / Man-day including VAT.

This amount of man-days has been adjusted by the discontinuation of 3 deliverables and expenses made so far.

The project management will be executed by the Dutch Standardisation Institute (NEN).

8. Criteria for selection of project team experts:

The Project team as a whole will need to have expertise in the following areas:

- Regulatory affairs in the area of pharmaceuticals
- Structured product information
- Pharmacovigilance
- The construction and content of dossiers supporting marketing authorization applications
- Information technology, particularly in the areas of messaging, databases and the handling of large volumes of unstructured information all across European and other territories.

Currently, the Project Team is seeking an expert who has excellent knowledge of English language (in writing), thorough knowledge of ISO/CEN drafting rules and medicines terminology. The candidate is requested to show the ability to achieve homogeneous set of 7 documents which are under development to become parallel international and European standards, preferably by drafting a general applicable model for the standards which are under development identified as part of "Identification of medicinal products". The candidate is requested to be in close communication with the task group who is working on the work items and in particular the designated editors of the work items.

Annex II

Technical Committee project Team³

1. Role / Definition

Completion of specified tasks for (a) specified period(s) of time with a limited number of experts within the context of the work programme of the Technical Committee (TC).

2. Reports to

Secretary General, or, by delegation, TC, Subcommittee (SC) or Working Group (WG).

3. Responsibilities

3.1 Prepares a draft programme of work when reference documents do not exist, for proposal to a TC if relevant, before approval by the Technical Board (BT)

3.2 Provides support to a TC on (a) specific and delimited task(s)

3.3 Carries out a study or investigation and produces a Report with recommendation to BT or TCs

4. Rights

Not applicable

5. Composition

Experts selected by the Secretary General.

6. Method of appointment / review

6.1 Call for applications to a project team is notified by the Secretary General, or his delegate, to the CEN Members with a time limit of 2 months. The CEN web site may also be used to promulgate the call.

6.2 The Secretary General (or his delegate) assisted by a Selection Committee selects the best qualified candidates following consultation with the Chairperson of the reference authority or relevant management level.

7. Mode of working

Through meetings and work by correspondence.

³ This Annex contains CEN rules regarding to a Technical Committee Project Team, please see for more information:
<http://www.cen.eu/boss/organization/profiles+-+index/tc+project+team/index.asp#>

Annex III
Application Form for the role of technical expert within the CEN Project Team
“Pharmacovigilance and Identification of medicinal products”

Please email this form accompanied by a short Curriculum Vitae to NEN
By 10 October 2008

Attn: Shirin Golyardi
Shirin.golyardi@nen.nl
+31-15-2690313

Applications should be made by email.

Name and contact details of the company:

Name and contact details of the expert candidate:

Expertise in the following areas:

- Excellent knowledge of English language (in writing)
- Thorough knowledge of ISO/CEN drafting rules and medicines terminology
- The ability to achieve homogeneous set of 7 documents which are under development to become parallel international and European standards, preferably by drafting a general applicable model for the standards which are under development identified as part of "Identification of medicinal products".
- The ability to work in close communication with the task group, responsible for the work items, and in particular the designated editors of the work items.
- The expert agrees with the proposed reimbursement level (650 Euro/man-day including VAT)

DO NOT FORGET TO ADD CURRICULUM VITAE