Specification for developing learning materials for SCOPE

1. INTRODUCTION

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to meet the EU legislative requirements.

Regulators are collaborating to improve skills and capability across the European network, which will help safeguard public health in both national territories and the EU as a whole.

The SCOPE Joint Action will run from 2013 until October 2016. It has been created to support operations of pharmacovigilance in Europe following new requirements introduced by the European pharmacovigilance legislation that came into effect in June 2012.

Funded by the Consumers, Health and Food Executive Agency (CHAFEA) and with contributions from Member States involved, SCOPE will gather information and expertise on how regulators in Member States run their national pharmacovigilance systems.

Using this information, SCOPE will develop and deliver guidance, training, tools and templates to support good practice. Through this approach SCOPE aims to support consistent approaches in pharmacovigilance operations in the EU network, which will benefit the safety monitoring of medicines and communications outputs, thereby helping to safeguard public health.

SCOPE has six high level objectives:

1. Enable member states to develop a fuller understanding of, and develop good practice in, reporting mechanisms for adverse drug reactions (ADRs).
2. Implement shared understanding of good practice in signal management across the EU network.
3. Define good practice in risk communications through the creation of a standardised toolkit.
4. Enable member states to understand and develop their quality management systems for pharmacovigilance.
5. Develop a competency framework to support exemplary pharmacovigilance throughout the product lifecycle.
6. Create a forum for interaction amongst European national competent authorities to strengthen regulatory collaboration. This will lead to improved understanding of the different challenges faced by member states.

Work packages
The SCOPE Joint Action work is divided into eight work packages, which target discrete elements or support the overall project.

1. Coordination
Lead: MHRA, UK
Objective: Responsible for the coordination and organisational aspects of SCOPE, delivery of the project on time, within budget and with high-quality outputs.

2. Communication and Dissemination
Lead: MHRA, UK
Objective: Responsible for effective dissemination of information regarding SCOPE's deliverables and the projects progress to target groups, partners and stakeholders.

3. Evaluation
Lead: INFARMED, Portugal
Objective: To evaluate SCOPE's deliverables and ensure consistency and value of training provided by SCOPE work packages.

4. ADR Collection
Lead: HALMED, Croatia
Objective: To provide Member States with a full understanding of, and good practice in, systems for collecting ADRs. A media toolkit will also be created to raise awareness of ADR reporting systems.

5. Signal Management
Lead: MEB, Netherlands
Objective: To develop an improved understanding of good practice for all aspects of signal management (detection, validation, assessment, management) across the EU network.

6. Risk Communications
Lead: AEMPS, Spain
Objective: To examine risk communication practices within the EU network in order understand the communication channels and tools used.

7. Quality Management Systems
Lead: OGYEI, Hungary
Objective: To increase existing knowledge on quality management system of PV staff at National Competent Authorities through provision of a training program and a toolkit which can be used for the further development.

8. Lifecycle Pharmacovigilance
Lead: AIFA, Italy
Objective: To examine pharmacovigilance assessments and recommend good practices to support high-quality assessment and capability of the EU network

2. REQUIREMENTS

Learning aim
Develop and deliver guidance, training, tools and templates to support good practice in pharmacovigilance assessment across the EU.

Learning outcome
Improve skills and capability of pharmacovigilance assessors across the European network to help safeguard public health in both national territories and the EU as a whole.

Evaluation of training
We require a method to evaluate the effectiveness of the training modules which would be provided, if chosen, by a learning management system (LMS).

However, suppliers are also asked to consider how we could evaluate without a LMS. For example, capturing the number and range of pharmacovigilance assessors who use the training modules and post-learning feedback through a user evaluation form etc.

Key audience
Pharmacovigilance teams in all 28 EU member states.

Someone working in a pharmacovigilance team is likely to have a degree in pharmacy, pharmacology, nursing, physiology, toxicology or another relevant scientific discipline.

The role is primarily responsible for the capture of adverse drug reaction (ADR) reports and pharmacovigilance signal detection and assessment procedures to ensure drug safety issues and risks to public health are identified and evaluated.

Website platform
The learning content will be delivered online, accessed from the existing SCOPE website. A 'Learning' tab needs to be added to the home page to link to the new content.

The learning content needs to be optimised and accessible through mobile devices (tablets and smart phones).

The learning content needs to meet recognised industry standards for accessibility.

The content will be moved to another website in the future so will need to be designed to be easily extracted or moved from the SCOPE website.

Authoring package
We require a simple authoring package solution that requires minimal / basic training so we can easily access and update content ourselves. Adobe Captivate would be our preference. We may require basic training in the package when appropriate in the project.

Learning management system
We would like to explore the option of a simple, easy-to-use learning management system so users can register, we can monitor usage, effectiveness and issue learning completion certificates, which could count towards professional CPD.

All learning content should be interactive material built to SCORM (Shareable Content Object Reference Model) standards.

Template-based system
We require branded templates designed so learning content can be uploaded in the future quickly and easily. The range of templates to be proposed by the supplier once the learning content has been reviewed.

We would require training and clear guidance notes on how to use any templates and systems developed.

Content structure and navigation
The learning content should be structured in a clear, intuitive and easily navigable way from the 'Learning' tab on the home page.

Learning content is required for the five scientific work packages (WP) which will form sub-sections of the Learning start page:

- WP 4 – ADR collection
- WP 5 – Signal management
- WP 6 – Risk communications
- WP 7 – Quality management systems
- WP 8 – Lifecycle pharmacovigilance

Content ownership
All content and the IPR is owned by SCOPE's sponsoring agencies – CHAFEA, EU.

Design
We require a strong, simple and consistent design across all the learning content materials / templates, developed using the SCOPE brand and design guidelines.

We require at least two design options to consider before finalising.

Text and language standards
Content will be supplied in MS Office format in English. But it will be coming from a range of member states and written to different styles so will need to be made consistent.

While technical terms cannot be changed, the final content should be edited by the supplier into plain, accessible English to recognised industry standards.

We may require the content to be translated into other European languages.

Learning presentation methods
We require a combination of presentation methods to provide information and learning to the user. The supplier is required to suggest the most effective, cost-efficient method based on the suitability of the raw content and the time constraints to complete the project.

The following are suggested methods:

a) Free or low-cost generic visuals / images from a stock library to improve accessibility and presentation of content where appropriate. Custom or bespoke images only commissioned as a last resort.

b) Graphical illustrations — still or animated graphics, photos, charts, and diagrams to reinforce content or illustrate processes.

c) Video and/or animations in a webcast to demonstrate tasks and procedures.

d) Case studies and/or problem-based learning — detailed explanation of a situation or problem that users must analyse and offer findings, recommendations, or solutions.

e) Guidance notes, FAQs, toolkits.

f) Audio — voiceover narration to reinforce onscreen text.

g) Integrated opportunities throughout the material that allow users to explore content, apply knowledge, and check understanding through questions, games, and activities.

h) As well as online learning material, templates should be developed for offline learning via presentation or hardcopy booklet.

Ideas exchange / discussion forum
We require a non-moderated area on the training site where users can post suggestions and exchange ideas.

User insight and testing
The content authors are experienced practitioners in the field and there has already been some testing of appropriateness and accessibility of content.

However, we also require the supplier establish up to three user groups to gain further insight into the accessibility of the content and most appropriate presentation methods. We would identify the users, and any insight work would be carried out through tele or video conferences etc.

The user groups would also be expected to test the learning material at stages throughout development.

Project management
The supplier will be responsible for project management of the project, initiating and running appropriate client meetings and delivery of the learning content to specification, agreed budget and time.

There will be a single UK point of contact from the SCOPE team for the supplier to liaise with on project management.

Indicative phased project timetable
Below is an indicative timetable which we expect will be subject to further negotiation with member state partners and the supplier.

The majority learning content work must be complete by the end of July 2016. The overall project finishes in October 2016 and there is no opportunity to run past this date.

Phase	Work package / deliverable	Time (content ready for publication)
1	**Lifecycle Pharmacovigilance** Lead: AIFA, Italy **Objective**: To examine pharmacovigilance assessments and recommend good practices to support high-quality assessment and capability of the EU network	Jan/Feb 2016
	REVIEW	Feb/Mar 2016
2	**Quality Management Systems** Lead: OGYEI, Hungary **Objective**: To increase existing knowledge on quality management system of PV staff at National Competent Authorities through provision of a training program and a toolkit which can be used for the further development.	Mar/Apr 2016
	REVIEW	Apr 2016
3	**ADR Collection** Lead: HALMED, Croatia **Objective**: To provide Member States with a full understanding of, and good practice in, systems for collecting ADRs. A media toolkit will also be created to raise awareness of ADR reporting systems.	Apr/May 2016
4	**Signal Management** Lead: MEB, Netherlands **Objective**: To develop an improved understanding of good practice for all aspects of signal management	May/Jun 2016

	(detection, validation, assessment, management) across the EU network.	
5	**Risk Communications** Lead: AEMPS, Spain **Objective**: To examine risk communication practices within the EU network in order understand the communication channels and tools used.	Jun/Jul 2016

3. PRICING AND EVALUATION

Budget
The budget for this project is up to a maximum of 140K EUROS.

Supplier proposals will be evaluated against the criteria and weighting shown below:

Criteria	**Weighting %**
1. Expertise and experience of developing complex information into engaging and interactive learning content, preferably in the healthcare area	45
2. Ability to manage a European-wide project involving multiple stakeholders, and deliver it on time	20
3. Creativity and innovation in providing innovative solutions to training and content development challenges	20
4. Value for money	15

Tender responses

Suppliers should ensure the following additional information is included in their response:

1. Details of their approach to developing learning content and working for each objective of the SCOPE project.

2. General supplier capabilities: background, qualifications, geographic presence, service offerings, organisational structure etc.

3. Technical expertise for content development and tactical delivery.

4. Examples of similar projects for other organisations.

5. Reference list – from companies you have worked with on similar projects that we can independently approach.

6. A proposed action plan and timetable for development and delivery of the project using the indicative timetable supplied.

7. Outline how this project will be managed, who will be the central contact, the proposed project team and structure. Please include CVs and details of why they are suitable for delivery of this project.

8. A clear breakdown of budget allocation.

Tender timetable

Date	**What**
23/10/15	Tender published
12/11/15	Supplier day / teleconference
23/11/15	Tender closes
30/11/15 (AM)	Tender evaluation
14/12/15	Supplier interviews
w.c 14/12/15	Contract awarded
13/1/16 (10.30am-12noon)	Kick of meeting with supplier