EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2014
EMA/INS/PhV/192237/2014

Union recommendations on the training and experience of inspectors performing pharmacovigilance inspections

Adopted by Pharmacovigilance Inspectors Working Group	21 March 2014
Date for coming into effect	01 June 2014

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8595
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Union recommendations on the training and experience of inspectors performing pharmacovigilance inspections

Table of contents

1. Introduction

This guideline provides recommendations on the minimal requirements for the training of inspectors performing pharmacovigilance inspections.

Member States may decide to implement supplementary national requirements.

2. Scope

The recommendations are relevant to inspectors who are involved in the conduct of pharmacovigilance inspections.

3. Legal basis

Article 14 of Commission Implementing Regulation (EU) No 520/2012 states:

"*2. All personnel involved in the performance of pharmacovigilance activities shall receive initial and continued training. The national competent authorities and the Agency shall keep training plans and records for documenting, maintaining and developing the competences of personnel and shall make them available for audit.*"

The guideline on good pharmacovigilance practices (GVP), Module III on pharmacovigilance inspections, section, III.B.9. qualification and training of inspectors states:

"*The inspectors should undergo training to the extent necessary to ensure their competence in the skills required for preparing, conducting and reporting inspections. They should also be trained in pharmacovigilance processes and requirements in such way that they are able, if not acquired by their experience, to comprehend the different aspects of a pharmacovigilance system.*

Documented processes should be in place in order to ensure that inspection competencies are maintained. In particular, inspectors should be kept updated with the current status of pharmacovigilance legislation and guidance.

Training and experience should be documented individually and evaluated according to the requirements of the applicable quality system of the concerned competent authority."

4. Appointment of inspectors

The inspectors should be officials of/or appointed by the Member State in accordance with national regulations and follow the provisions of the national competent authority.

The appointment should be made on the basis of the following items:

- Scientific training in the healthcare field (medicine, pharmacy, veterinary medicine), or,
- Other life sciences with relevance to pharmacovigilance

Experience in post-authorisation and/or safety monitoring in clinical research and knowledge of current applicable legislation and guidelines may be desirable.

5. Training

Training can be defined as a learning process that involves the acquisition of knowledge, skills and competencies. It also means sharpening of skills, concepts, rules, or changing of attitudes and behaviours to enhance the performance of individuals.

The inspectors should undergo basic training to the extent necessary to ensure their competence in the skills required for planning, carrying out and reporting inspections. Inspectors must have competencies to fulfil the requirements of agreed inspection procedures and guidance.

In addition to the basic training required for becoming an inspector, the need to continue training beyond the initial appointment is recognised. This would involve maintaining and updating one's skills throughout one's working life.

The recommendations for training presented below relate to the basic training requirements for pharmacovigilance inspectors and a continued on-the-job training approach.

Training and experience should be documented individually and evaluated against the requirements of the system in place at the Competent Authority/Inspectorate. Competency should be gained through an assessment process that would include review of the training programme and the capability of the inspector to plan, notify, conduct and report on inspections.

5.1. Basic training process

For newly appointed inspectors to take part in pharmacovigilance inspections, it is recommended that a training programme be put in place.

The inspector may receive training in a variety of ways that may include:

- Review of relevant matters in the regulatory field including: European Union (EU) and national pharmaceutical legislation, good pharmacovigilance practice, knowledge of the Union procedures, inspection techniques, EU databases relevant to pharmacovigilance.
- 'On-the-job' through observing and then participating in inspections with experienced inspectors. The practice should include the peer review of inspection reports.
- Classroom style through 1 to 1 or group training sessions.
- Attendance at internal / external conferences.
- Attendance of the EU pharmacovigilance inspectors training course.

The training programme should be documented and customised according to the inspector's experience and skills. The inspector should, through suitable means, demonstrate his/her knowledge and capability to use the necessary management skills required for conducting and leading an inspection (planning, notification, conduct and reporting).

5.2. Continued development and maintenance of competence

Following his/her appointment, the pharmacovigilance inspector continues to develop their inspection skills including involvement in more complex inspections. When appropriate, joint inspections with other inspectors of the same Member State or of other Member States should be considered. The peer review of inspection reports should be continued according to the practice in place at the Member State concerned. This may be done on a sample of reports.

The inspector should keep up to date with the current status of the pharmacovigilance legislation and guidance. This may be achieved through participation in courses, seminars, meetings and conferences.

6. Harmonisation within the EEA

In order to promote harmonisation in the interpretation of the pharmacovigilance requirements, principles and compliance, the national competent authority/inspectorate's management should facilitate training activities, including on- the-job training, at national and European Union level.

Consultations with the staff of other inspectorates and joint inspections or training visits are encouraged and may be used as a training method.

The European network should facilitate the exchange of information between inspectorates of different disciplines and encourage inspectors to gain practical experience, in closely related disciplines e.g. pharmacovigilance assessment, good manufacturing practice (GMP) inspection, good clinical practice (GCP) inspection, computerised data recording and analyses and requirements in relation to medicinal products for investigational use, where appropriate.

References

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Union code relating to medicinal products for human use, as amended.
- Commission Implementing Regulation (EU) No 520/2012, on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
- Guideline on good pharmacovigilance practices (GVP) - Module III – pharmacovigilance inspections.
- Union procedure on the preparation, conduct and reporting of EU pharmacovigilance inspections.