



Guideline on training and qualification of inspectors performing inspections of wholesale distributors

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Title	Guideline on training and qualification of inspectors performing inspections of wholesale distributors
Date of adoption	May 2023
Date of entry into force	1 January 2024
Supersedes	version adopted November 2010
Reason for revision	Modifications were introduced as a result of the entry into application of Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
Notes	Not applicable
Last publication date:	1 August 2024
Document version	1

Guideline on training and qualification of inspectors performing inspections of wholesale distributors

1. Summary

Taking into account the paramount importance of the management of inspection services, this guideline establishes some requirements concerning experience, training and qualifications of inspectors performing inspections of wholesale distributors.

Objectivity, confidentiality, professional integrity, knowledge of technical matters, knowledge of legislation, and auditing skills are the main requirements of inspectors.

Inspectors should be very well trained in all aspects of the distribution of medicinal products and in the way of conducting an inspection.

The guideline provides information on minimal requirements and is intended to be supplementary to any national requirements.

2. Scope

This guideline defines the training and qualification criteria required for an inspector who shall conduct an inspection to verify compliance with the legal requirements relating to wholesale distribution¹ for the competent authority of the Member State concerned. It also identifies ongoing training needs of inspectors as they progress from 'entry level' to 'expert' across a number of inspection specialities, each speciality having their own specific technical, legislative and practical inspection training needs.

3. Background

3.1 General Aspects

Member States should appoint inspectors to inspect wholesale distributor sites concerned by Directive 2001/83/EC and Regulation 2019/6. There should be sufficient resources at all levels to meet, effectively and efficiently, the EU requirements of verifying compliance with the legal requirements relating to the wholesale distribution of medicinal products.

The inspectors shall be officials of or appointed by the competent authorities of the Member States in accordance with national regulations and follow the provisions for the national competent authority. All inspectors should be competent to carry out their assigned duties and receive appropriate training. When needed teams of inspectors may be nominated comprising inspectors with appropriate qualifications and experience to collectively fulfil the requirements necessary for conducting the inspection.

The inspectors should be made aware of and maintain confidentiality whenever they gain access to confidential information as a result of inspections according to applicable national laws or European requirements.

3.2 Personal Qualities

The personal skills of an inspector are important in helping to achieve the objectives of the inspections.

During an inspection the inspector should help in creating a positive atmosphere. Inspectors need to remain objective during the inspection and in this context should answer questions or provide clarification but avoid entering into the role of a consultant.

The inspector should have a high personal integrity, maturity, be open-minded, understanding of

¹ This includes compliance with Good Distribution Practice for medicinal products for human use and Good Distribution Practice for veterinary medicinal products.

complexity, possess sound judgement, assertiveness, analytical skills and tenacity and have the ability to perceive situations in a realistic way.

The inspector should have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their official recognized language.

4. Qualification and training

4.1 Qualification

Inspectors shall be qualified according to national requirements.

4.2 Training

The inspectors should undergo training to the extent necessary to ensure their competence in the skills required for planning, carrying out and reporting inspections.

Training and experience should be documented individually and evaluated within the requirements of the applicable quality system of the Competent Authority/Inspectorate.

4.2.1 Basic training

Inspectors should be capable of demonstrating their understanding of relevant matters in the regulatory field, including:

- Good Distribution Practice (GDP);
- Good Manufacturing Practices (GMP) basic knowledge;
- Applicable EU and national legislation;
- Knowledge of the Compilation of Union Procedures;
- Knowledge of the organisation and quality system of the national competent authorities;
- Knowledge of wholesaling principles and roles of actors in the supply chain;
- The general principles of Quality Management Systems;
- Marketing, manufacturing and wholesale distribution authorisation systems and their relationships;
- Inspection techniques including skills required for managing an inspection, such as planning, organising, and evaluation of findings and reporting, communicating or providing feed back to the inspectee. These may be acquired by attending relevant course(s) and/or by accompanying and/or be guided by senior inspectors during inspections;
- Interrelation of inspection, sampling and analysis, and licensing, as appropriate;
- An awareness of trends in falsified medicines.

4.2.2 In-service training

After recruitment and in addition to their basic training, new inspectors should be trained by an assigned mentor. The theory of inspection should be explained and the practice should be shown in the field, so that concrete examples of the meaning and of the goals of inspections are given and can be discussed. New inspectors should participate but only as observers, in on the spot inspections carried out during their basic training.

Besides this and where needed, training courses in auditing techniques and communications, reporting, languages, legal matters and management should be organised by national inspectorates.

Prior to assuming responsibility for performing inspections of wholesale distributors the new inspector should have gained experience by participation as team member in inspections led by

a senior inspector. Preferably, the inspector should start with inspections as a member of a team and then deal progressively with more complex inspections to be able to act as a team leader. This should be recorded within the requirements of the applicable quality systems of the Competent Authority/Inspectorate.

The inspector should, through suitable means, demonstrate his or her knowledge and capability of using the necessary management skills required in execution of an inspection, i.e. planning, announcing, conducting and reporting an inspection.

The inspector should document and demonstrate his or her capability to write inspection reports according to both EU and national requirements.

4.2.3 Continuous training

Considering the expanding technologies in the wholesale distribution arena, the ever more frequent utilisation of automatic and computerised systems such as warehouse inventory management systems, inspectors should also receive continuous training. This could be achieved through participation in courses, seminars, meetings and conferences organised either by the national inspectorates or by national or international scientific organisations. When appropriate, joint inspections or training visits with other inspectors of the same Member State or of other Member States may be a useful training tool.

All inspectors performing inspections of wholesale distributors should aim to spend five days training per year. GDP aspects should be covered in this training. This ongoing training may include training inspections, courses, symposia, conferences, etc. These training days should be planned and documented.

5. Maintenance of competence

Inspectors should have their performance and qualifications periodically reviewed and assessed within the requirements of the applicable quality system of the Competent Authority/Inspectorate. Their competence should be maintained and updated by continuous training as described in 4.2.3. This should be documented and its effectiveness assessed.

6. Harmonisation within the EEA

In order to promote international harmonisation in the interpretation of the principles and compliance, the wholesale distribution inspection program management should facilitate training activities, including on the job training, at national and international levels.

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

The Competent Authority/Inspectorate should also facilitate and encourage the exchange of information and practical experience gained by inspectors in the field of wholesale distribution.