DECISION

No. 10/22.04.2013

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

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.04.2013, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article. – The Guideline on training and qualification of inspectors performing inspections of wholesale distributors is approved, in accordance with the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no. 10/22.04.2013

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

CHAPTER I
Introduction

Art. 1. – This Guideline is a translation into Romanian and a transposition of the Guideline on training and qualification of inspectors performing inspections of wholesale distributors which is part of the Compilation of Community Procedures on Inspections and Exchange of Information EMA/INS/GMP/321252/2012 Rev 15 published by the European Medicines Agency (EMA).

CHAPTER II
Summary

Art. 2. – (1) 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.

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

(3) Inspectors must be very well trained in all aspects of the distribution of medicinal products and in the way of conducting an inspection.

(4) This guideline provides information on minimal requirements; Member States may decide to add supplementary national requirements.

CHAPTER III
Scope

Art. 3. – This guideline applies to the training and qualifications required for an inspector of the National Agency for Medicines and Medical Devices (NAMMD) who shall conduct an inspection to verify compliance with the legal requirements for wholesale distribution[1]. Moreover, it identifies the requirements for ongoing training of inspectors as they advance from the "basic" to the "expert" level throughout a number of inspection fields, each field having its own technical, legislative and practical training requirements.

CHAPTER IV
Background

Art. 4. – General aspects

(1) The NAMMD appoints inspectors to inspect the sites of distributors, as specified in Law 95/2006.

[1] This includes compliance with the Good Distribution Practice for medicinal products for human use.

(2) There must be sufficient resources at all levels to meet, effectively and efficiently, the EU requirements of verifying compliance with the legal requirements for the wholesale distribution of medicinal products.

(3) The inspectors are officially appointed by the NAMMD in accordance with legal requirements.

(4) All inspectors must be competent to carry out their assigned duties and receive appropriate training.

(5) 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.

(6) The inspectors are to be made aware of and maintain confidentiality whenever they gain access to confidential information during inspections in accordance with the national legislation and European requirements.

Art. 5. – Personal qualities

(1) The inter-personal skills of an inspector are important in helping to achieve the objectives of inspections.

(2) During an inspection, the inspector should help in creating an open 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.

(3) The inspector should have a high level of personal integrity, maturity, be open-minded, understanding of complexity, possess sound judgement, assertiveness, analytical skills and tenacity and have the ability to perceive situations in a realistic way.

(4) The inspector should demonstrate competence in clearly and fluently expressing concepts and ideas orally and in writing in Romanian.

CHAPTER V
Qualification and training

Art. 6. – Qualification

Inspectors are qualified in accordance with national requirements.

Art. 7. – Training

(1) The inspectors have undergone training to the extent necessary to ensure their competence in the skills required for planning, carrying out and reporting inspections.

(2) The training and experience should be documented individually and evaluated within the requirements of the applicable quality system of the Inspectorate.

Art. 8. – Basic training

(1) Moreover, in order to be appointed as inspectors, the candidates must demonstrate their knowledge of the relevant matters in the pharmaceutical field, including:

- Good Distribution Practice (GDP);
- Basic knowledge of the Good Manufacturing Practice (GMP);
- Community and national pharmaceutical legislation;
- Compilation of Community procedures;
- Organisation and quality systems of national Competent Authorities;
- Principles of wholesale distribution and roles of the actors involved in the distribution system;
- Principles of quality management systems;
- Marketing, manufacturing and wholesale distribution authorisation systems and their relationship;

- Inspection techniques, including the skills required for inspection management i.e. planning, organisation, assessment of deficiencies and reporting, communication and information for the inspected entity. Such skills can be acquired by attending relevant courses and or/by accompanying and/or guided by qualified GMP inspectors during inspection;

- Interrelation of licensing, inspection, sampling and analysis, as required;

- Acknowledging the counterfeiting trend.

Art. 9. – Further training

(1) After recruitment and in addition to their basic training, new inspectors are trained by assigned senior inspectors. 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 training.

(2) Beside this and where needed, training courses in inspection techniques and audit, communication, reporting, languages, legal matters and management should be organised by national inspectorates.

(3) Prior to assuming responsibility for performing inspections at wholesale distributors, the new inspector should have gained experience by participation as team member in inspections led by senior inspectors. Preferably, the inspector starts with national GMP 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 is recorded within the requirements of the applicable quality system of the Inspectorate.

(4) Through suitable means, the inspector is to demonstrate his/her knowledge and capability of using the necessary management skills required in the conduct of an inspection, i.e. planning, announcing, conducting and reporting an inspection.

(5) The inspector demonstrates his/her capability to write reports in accordance with national and EU requirements.

Art. 10. – Continuous training

(1) Considering the rapid implementation of new manufacturing technologies, the ever more frequent utilisation of automatic and computerized systems both in production and quality control of medicinal products, inspectors also receive continuous training. This can be done by participating to courses, seminars, meetings and conferences organised by national inspectorates or by national/international scientific organisations.

(2) Where needed, joint inspections or training visits with other inspectors from Romania/other Member States could be a useful tip.

(3) The target of all inspectors performing inspections at wholesale distributor sites should be 5 days of training per year. This training should also include DP issues. This ongoing training may include training inspections, courses, symposia, conferences etc. These training days are planned and documented.

CHAPTER VI
Maintenance of competence

Art. 11. – (1) Inspectors have their performance and qualifications periodically reviewed within the requirements of the applicable quality system of the Inspectorate.

(2) Their competence must be maintained and updated by ongoing training, as described under Art. 10. This is documented and its effectiveness assessed.

CHAPTER VII
Harmonisation within the European Economic Area (EEA)

Art. 12. – (1) In order to promote international harmonisation in the interpretation of the principles and compliance, the Inspectorate's management facilitates training activities, including on the job training, at national and international levels.

(2) Consultations with the staff of other inspectorates and joint inspections or training visits are useful in this context and are to be encouraged.

(3) The management should also facilitate the exchange of information and practical experience gained by inspectors in the field of wholesale distribution.

CHAPTER VIII
Legal references

- Law 95/2006 Title XVII- The medicinal product
- Compilation of community procedures on inspections and exchange of information (Art. 3.3 of Directive 2003/94/EC transposed through Art. 4 of Order of the Minister of Public Health no. 905/2006 on the Principles and guidelines for good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use)