Issuer:	Minister of Social Affairs
Type:	regulation
In force from:	21.10.2005
In force until:	In force
Translation published:	08.10.2014

Requirements for Qualifications of Competent Persons and List of Evidence of Formal Qualification

Passed 11.03.2005 No. 42
RTL 2005, 32, 459
Entry into force 25.03.2005

Amended by the following acts

Passed	Published	Entry into force
07.10.2005	RTL 2005, 105, 1604	21.10.2005

This Regulation is established on the basis of subsection 53 (6) of the Medicinal Products Act (RT I 2005, 2, 4).

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application

This Regulation establishes the requirements for competent persons employed in a place of business holding an activity licence for the handling of medicinal products (hereinafter a company), and the list of evidence of formal qualification.

Chapter 2
LIST OF EVIDENCE OF FORMAL QUALIFICATION OF COMPETENT PERSON

§ 2. List of evidence of formal qualification of competent person to be submitted by applicant for activity licence

The applicant for activity licence shall submit to the State Agency of Medicines copies of the following documents providing evidence of qualification of the competent person:
1) document certifying education;
2) diploma supplement;
3) employment record book, employment contract or another document certifying employment, specifying the company's name, location and field of activity;
4) documents certifying in-service training.

Chapter 3
REQUIREMENTS FOR QUALIFICATION OF COMPETENT PERSON

§ 3. Requirements for qualification of competent person employed in company engaged in manufacture of full blood and blood components

A person with the following qualification may be employed as a competent person in a company engaged in the manufacture of full blood and blood components:

1) an academic degree of a doctor or biologist acquired in a university, or a corresponding foreign qualification;
2) at least three years of professional experience in the last five years in the field of quality control in a company holding an activity licence for the manufacture of full blood and blood components.

§ 4. Requirements for qualification of competent person employed in company engaged in manufacture of active substances and medicinal gases

(1) A person with the following qualification may be employed as a competent person in a company engaged in the manufacture of active substances and medicinal gases:
1) an academic degree of a doctor, dispensing chemist or chemist acquired in a university, or a higher education in a technical speciality or a corresponding foreign qualification;
2) at least one year of professional experience in the last five years in the field of quality control, including good manufacturing practice, in a company holding an activity licence for the manufacture of medicinal products.

(2) Employment in a company engaged in the packaging of herbal substances, in the manufacture of full blood and blood components or in the change of packaging or labelling shall not be considered as professional experience in the meaning of clause 2 of subsection (1).

§ 5. Requirements for qualification of competent person employed in company engaged in manufacture of proprietary medicinal products, intermediate products, medicinal products intended for clinical trials and other medicinal products not specified in sections 3 and 4

(1) A person with the following qualification may be employed as a competent person in a company engaged in the manufacture of proprietary medicinal products, intermediate products, medicinal products intended for clinical trials and other medicinal products not specified in sections 3 and 4:
1) an academic degree of a dispensing chemist, doctor, veterinarian, chemist or biologist acquired in a university, or a corresponding foreign qualification;
2) in the case of persons with the qualification of a dispensing chemist, at least one year, and in the case of persons with the qualification of a doctor, veterinarian, chemist or biologist, at least two years of professional experience in the last five years in the field of qualitative analysis of medicinal products, quantitative analysis of active substances and quality control of medicinal products, including implementation of good manufacturing practice, in a company holding an activity licence for the manufacture of medicinal products, or, in the case of a person from another Member State of the European Economic Area, the right to fulfil the duties of the competent person in the Member State.

(2) Employment in a company engaged in the packaging of herbal substances, manufacture of full blood and blood components or medicinal gases shall not be considered as professional experience in the meaning of clause 2 of subsection (1).

(3) The preparation and experience of the competent person shall comply with the manufacturing activities.

(4) A competent person, whose professional experience has been gained in a company engaged merely in the change of packaging or labelling, shall not serve as a competent person in a company engaged in other manufacturing activities.

(5) In order to be employed as a competent person in a company engaged in the manufacture of sterile pharmaceutical forms, a person shall have at least one year of professional experience in a company holding an activity licence for the manufacture of sterile pharmaceutical forms, and shall have passed in- service training in the manufacture of sterile medicinal products.

§ 6. Requirements for qualification of competent person employed in company engaged in packaging of herbal substances

A person with the following qualification may be employed as a competent person in a company engaged in the packaging of herbal substances:
1) education of a doctor, dispensing chemist, biologist, pharmacist, agronomist or horticulturist, or a corresponding foreign qualification;
2) at least one year of professional experience in a company handling medicinal plants, general pharmacy, hospital pharmacy or the relevant educational or research institution.

§ 7. Requirements for qualification of competent person employed in company engaged in wholesale of medicinal products

(1) A person with the following qualification may be employed as a competent person in a company engaged in wholesale of medicinal products:
1) an academic degree of a dispensing chemist acquired in a university, or a corresponding foreign qualification;
2) at least one year of professional experience in a company holding an activity licence for the wholesale of medicinal products or in a general pharmacy.

(2) A person with the following qualification may be employed as a competent person of a wholesaler handling veterinary medicinal products:
1) an academic degree of a dispensing chemist or veterinarian acquired in a university, or a corresponding foreign qualification;
2) at least one year of professional experience in a company holding an activity licence for the wholesale of medicinal products, a general pharmacy or a veterinary pharmacy.

§ 8. Requirements for qualification of competent person employed in company holding activity licence for provision of pharmacy services

(1) A person with the following qualification may be employed as a competent person in a general pharmacy and hospital pharmacy:
1) an academic degree of a dispensing chemist acquired in a university, or a corresponding foreign qualification;
2) at least three years of professional experience in the provision of pharmacy services in a general pharmacy or hospital pharmacy in the last five years.
[RTL 2005, 105, 1604 – entered into force 21.10.2005]

(2) A person with the following qualification may be employed as a competent person in a veterinary pharmacy:
1) an academic degree of a dispensing chemist or veterinarian acquired in a university, or a corresponding foreign qualification;
2) at least one year of professional experience in the provision of pharmacy services or as a veterinarian in the last five years.
[RTL 2005, 105, 1604 – entered into force 21.10.2005]

§ 9. Implementing provisions

(1) The requirements established in this Regulation for the qualification of a competent person shall not be applied to a person who, at the moment of entry into force of the Medicinal Products Act, was serving as the head of the same pharmacy in a company holding an activity licence for retail sale of medicinal products, fulfilling the duties of a competent person and serving as the person responsible for quality control in a company holding an activity licence for wholesale of medicinal products or as a qualified person in a company holding an activity licence for manufacture of medicinal products. The person may continue employment as a competent person in the corresponding field, provided that the competent person for manufacturing complies with the requirement established by subsection 53 (3) of the Medicinal Products Act.
[RTL 2005, 105, 1604 – entered into force 21.10.2005]

(2) The professional experience of a person appointed to act as a competent person for the wholesale of medicinal products in a company holding an activity licence for manufacture of medicinal products at the time of entry into force of the Medicinal Products Act may have been acquired in the same manufacturing company.

(3) Where a wholesaler of medicinal products applies for an activity licence for manufacture of medicinal products for the purpose of changing labelling or packaging, a person whose professional experience has been gained as a person responsible for the change of labelling or packaging of medicinal products in a company holding an activity licence for the wholesale of medicinal products may be applied as the competent person for manufacturing in case of applications for activity licence until 1 July 2005.
* Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp 67–128); Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp 1–6); Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 033, 08/02/2003, pp 0030–0040)