Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance)

TITLE III

FREEDOM OF ESTABLISHMENT

CHAPTER III

Recognition on the basis of coordination of minimum training conditions

Section 7

Pharmacist

Article 44

Training as a pharmacist

1 Admission to a course of training as a pharmacist shall be contingent upon possession of a diploma or certificate giving access, in a Member State, to the studies in question, at universities or higher institutes of a level recognised as equivalent.

[[F1]2 Evidence of formal qualifications as a pharmacist shall attest to training of at least five years' duration, which may in addition be expressed with the equivalent ECTS credits, comprising at least:

a four years of full-time theoretical and practical training at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university;

b during or at the end of the theoretical and practical training, six-month traineeship in a pharmacy which is open to the public or in a hospital under the supervision of that hospital's pharmaceutical department.

The training cycle referred to in this paragraph shall include at least the programme described in point 5.6.1 of Annex V. The Commission shall be empowered to adopt delegated acts in accordance with Article 57c concerning the amendment of the list set out in point 5.6.1 of Annex V with a view to adapting it to scientific and technical progress, including the evolution of pharmacological practice.

The amendments referred to in the second subparagraph shall not entail an amendment of existing essential legislative principles in Member States regarding the structure of professions as regards training and conditions of access by natural persons. Such amendments shall respect the responsibility of the Member States for the organisation of education systems, as set out in Article 165(1) TFEU.**]**

3 Training for pharmacists shall provide an assurance that the person concerned has acquired the following knowledge and skills:

a adequate knowledge of medicines and the substances used in the manufacture of medicines;

b adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products;

c adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products;

d adequate knowledge to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge;

e adequate knowledge of the legal and other requirements associated with the pursuit of pharmacy.

Textual Amendments

F1 Substituted by Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') (Text with EEA relevance).

Article 45

Pursuit of the professional activities of a pharmacist

1 For the purposes of this Directive, the activities of a pharmacist are those, access to which and pursuit of which are contingent, in one or more Member States, upon professional qualifications and which are open to holders of evidence of formal qualifications of the types listed in Annex V, point 5.6.2.

[[F1]2 The Member States shall ensure that the holders of evidence of formal qualifications in pharmacy at university level or a level recognised as equivalent, which satisfies the requirements of Article 44, are able to gain access to and pursue at least the following activities, subject to the requirement, where appropriate, of supplementary professional experience:

a preparation of the pharmaceutical form of medicinal products;

b manufacture and testing of medicinal products;

c testing of medicinal products in a laboratory for the testing of medicinal products;

d storage, preservation and distribution of medicinal products at the wholesale stage;

e supply, preparation, testing, storage, distribution and dispensing of safe and efficacious medicinal products of the required quality in pharmacies open to the public;

f preparation, testing, storage and dispensing of safe and efficacious medicinal products of the required quality in hospitals;

g provision of information and advice on medicinal products as such, including on their appropriate use;

h reporting of adverse reactions of pharmaceutical products to the competent authorities;

i personalised support for patients who administer their medication;

j contribution to local or national public health campaigns.**]**

3 If a Member State makes access to or pursuit of one of the activities of a pharmacist contingent upon supplementary professional experience, in addition to possession of evidence of formal qualifications referred to in Annex V, point 5.6.2, that Member State shall recognise as sufficient proof in this regard a certificate issued by the competent authorities in the home Member State stating that the person concerned has been engaged in those activities in the home Member State for a similar period.

4 The recognition referred to in paragraph 3 shall not apply with regard to the two-year period of professional experience required by the Grand Duchy of Luxembourg for the grant of a State public pharmacy concession.

5 If, on 16 September 1985, a Member State had a competitive examination in place designed to select from among the holders referred to in paragraph 2, those who are to be authorised to become owners of new pharmacies whose creation has been decided on as part of a national system of geographical division, that Member State may, by way of derogation from paragraph 1, proceed with that examination and require nationals of Member States who possess evidence of formal qualifications as a pharmacist referred to in Annex V, point 5.6.2 or who benefit from the provisions of Article 23 to take part in it.

Textual Amendments

F1 Substituted by Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') (Text with EEA relevance).