



COMMISSION DELEGATED DIRECTIVE (EU) 2024/782

of 4 March 2024

amending Directive 2005/36/EC of the European Parliament and of the Council as regards the minimum training requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ⁽¹⁾, and in particular Article 21(6), second subparagraph, Article 31(2), second subparagraph, Article 34(2), second subparagraph, and Article 44(2), second subparagraph, thereof,

Whereas:

- (1) The harmonised minimum training requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist are currently set out in Articles 31, 34, and 44 of Directive 2005/36/EC as well as in points 5.2.1, 5.3.1 and 5.6.1 of Annex V to that Directive.
- (2) In its 2011 Green Paper on the modernisation of Directive 2005/36/EC ⁽²⁾, the Commission acknowledged the need to modernise the harmonised minimum training requirements in different phases.
- (3) In the context of the amendment of Directive 2005/36/EC through Directive 2013/55/EU of the European Parliament and of the Council ⁽³⁾, national authorities, academic institutions and professional organisations indicated that the professions covered by Title III, Chapter III of the Directive have significantly evolved since their minimum training requirements were harmonised.
- (4) While Directive 2013/55/EU reviewed to a certain extent the harmonised minimum training requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist, no substantial changes were made to the training programmes listed in points 5.2.1, 5.3.1 and 5.6.1 of Annex V to Directive 2005/36/EC or to the list of knowledge and skills to be acquired during training laid down in Articles 31(6), 34(3) and 44(3) of that Directive.
- (5) Instead, Article 21(6) of Directive 2005/36/EC, as amended by Directive 2013/55/EU, provided the Commission with delegated powers to introduce, in accordance with its Article 57c, updates to the minimum training requirements in order to adapt them to generally acknowledged scientific and technical progress to reflect the evolution of Union law directly affecting the professionals concerned.
- (6) The Commission has assessed whether the minimum training requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist, as set out in Directive 2005/36/EC, should be updated in light of generally acknowledged scientific and technical progress.

⁽¹⁾ OJ L 255, 30.9.2005, p. 22, ELI: <http://data.europa.eu/eli/dir/2005/36/oj>.

⁽²⁾ Green Paper, Modernising the Professional Qualifications Directive, COM(2011)367 final of 22 June 2011.

⁽³⁾ 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') (OJ L 354, 28.12.2013, p. 132, ELI: <http://data.europa.eu/eli/dir/2013/55/oj>).

- (7) To assist the Commission in its assessment, three studies have been carried out. The aim of those studies was to explore the developments of training requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist in all Member States and European Free Trade Association States (EFTA States). For that purpose, data was collected at Union and national level through desk research and targeted stakeholder consultations. The data collection focused on several developments in training requirements at national level: (i) scientific and technical advancements affecting the professions of nurse responsible for general care, dental practitioner and pharmacist; (ii) training programmes as well as knowledge and skills that go beyond the minimum training requirements laid down in Directive 2005/36/EC and that reflect any adaptation to scientific and technical advancements.
- (8) A comparative assessment of the data collected was carried out during the studies. It focused on developments in and commonalities between training requirements across all Union Member States and EFTA States in light of generally acknowledged scientific and technical progress. For that purpose, a working definition of 'generally acknowledged' scientific and technical progress was created, consisting of scientific and technical advancements that have been noted in at least 16 Member States and EFTA States.
- (9) The results of the studies were presented to relevant stakeholders during workshops and meetings of the group of coordinators for the recognition of professional qualifications. Based on the feedback received, the conclusions of the studies were drafted, suggesting updates to the minimum training requirements set out in Directive 2005/36/EC in respect of training programmes as well as knowledge and skills.
- (10) The study on nurses responsible for general care ⁽⁴⁾ identified the following generally acknowledged scientific and technical advancements in training programmes in Member States and EFTA States that were not represented or not sufficiently represented in the current minimum training requirements set out in Directive 2005/36/EC: person-centred care theory, management theory applied to nursing, evidence-based practice, e-health, and technical innovations related to healthcare and nursing methods.
- (11) The study on dental practitioners ⁽⁵⁾ identified the following generally acknowledged scientific and technical advancements in training programmes in Member States and EFTA States that were not represented or not sufficiently represented in the current minimum training requirements set out in Directive 2005/36/EC: implantology, gerodontology, interprofessional collaborative care, dental public health – community oral health, practice management, genetics and genomics, immunology, regenerative medicine/dentistry and digital technology in dentistry.
- (12) The study on pharmacists ⁽⁶⁾ identified the following generally acknowledged scientific and technical advancements in training programmes in Member States and EFTA States that were not represented or not sufficiently represented in the current minimum training requirements set out in Directive 2005/36/EC: biopharmaceutical technology and biotechnology, genetics and pharmacogenomics, immunology, clinical pharmacy, pharmaceutical care, social pharmacy, epidemiology and pharmacoepidemiology, pharmacy practice, inter- and multidisciplinary collaboration, pathology and pathophysiology, health economics and pharmacoeconomics, information technology and digital technology.

⁽⁴⁾ European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Mapping and assessment of developments of one of the sectoral professions under Directive 2005/36/EC – Nurse responsible for general care – Final study*, Publications Office of the European Union, 2020.

⁽⁵⁾ European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Mapping and assessment of developments for sectoral professions under Directive 2005/36/EC – The profession of dental practitioner*, Publications Office of the European Union, 2022.

⁽⁶⁾ European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Mapping and assessment of developments for sectoral professions under Directive 2005/36/EC – The profession of pharmacist*, Publications Office of the European Union, 2022.

- (13) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ⁽⁷⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents to explain the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (14) Directive 2005/36/EC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2005/36/EC

Directive 2005/36/EC is amended as follows:

- (1) in Article 31, paragraph 6 is replaced by the following:
- ‘6. Training for nurses responsible for general care shall provide an assurance that the professional in question has acquired the following knowledge and skills:
- (a) comprehensive knowledge of the sciences on which general nursing is based, including sufficient understanding of the structure, physiological functions and behaviour of healthy and sick persons, and of the relationship between the state of health and the physical and social environment of the human being;
 - (b) knowledge of the nature and ethics of the profession and of the general principles of health and nursing;
 - (c) adequate clinical experience; such experience, which should be selected for its training value, should be gained under the supervision of qualified nursing staff and in places where the number of qualified staff and equipment are appropriate for the nursing care of the patient;
 - (d) the ability to participate in the practical training of health personnel and experience of working with such personnel and with members of other professions in the health sector;
 - (e) the ability to provide individualised nursing care and to empower patients, relatives and other relevant persons in relation to self-care and leading a healthy lifestyle;
 - (f) the ability to develop an effective leadership approach and decision-making skills;
 - (g) knowledge of the technical innovations related to healthcare and nursing methods.’;
- (2) in Article 34, paragraph 3 is replaced by the following:
- ‘3. Basic dental training shall provide an assurance that the person in question has acquired the following knowledge and skills:
- (a) adequate knowledge of the sciences on which dentistry is based and a good understanding of scientific methods, including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data;
 - (b) adequate knowledge of the constitution, physiology and behaviour of healthy and sick persons as well as the influence of the natural and social environment on the state of health of the human being, in so far as these factors affect dentistry;

⁽⁷⁾ OJ C 369, 17.12.2011, p. 14.

- (c) adequate knowledge of the structure and function of the teeth, mouth, jaws and associated tissues, both healthy and diseased, and their relationship to the general state of health and to the physical and social well-being of the patient;
- (d) adequate knowledge of clinical disciplines and methods, providing the dentist with a coherent picture of anomalies, lesions and diseases of the teeth, mouth, jaws and associated tissues and of preventive, diagnostic and therapeutic dentistry;
- (e) suitable clinical experience under appropriate supervision;
- (f) adequate knowledge of digital dentistry and a good understanding of its use and safe application in practice.

This training shall provide him with the skills necessary for carrying out all activities involving the prevention, diagnosis and treatment of anomalies and diseases of the teeth, mouth, jaws and associated tissues.;

- (3) in Article 44, paragraph 3 is replaced by the following:

‘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;
- (f) adequate knowledge of clinical pharmacy and pharmaceutical care, as well as the skills of their practical application;
- (g) adequate knowledge and skills of public health and its repercussions in health promotion and disease management;
- (h) adequate knowledge and skills on inter- and multidisciplinary collaboration, interprofessional practice and communication;
- (i) adequate knowledge of information technology and digital technology and skills on its practical application.’;

- (4) Annex V is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 4 March 2026 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3***Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 4 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex V is amended as follows:

(1) point 5.2.1 is replaced by the following:

‘5.2.1 Training programme for nurses responsible for general care

The training leading to the award of a formal qualification of nurses responsible for general care shall consist of the following two parts.

A. Theoretical instruction

a. Nursing:

- Nature, ethics and general principles of health and nursing, including person-centred care theories
- Nursing principles in relation to:
 - general and specialist medicine
 - general and specialist surgery
 - childcare and paediatrics
 - maternity care
 - mental health and psychiatry
 - care of the elderly and geriatrics
- Evidence-based nursing practice and research

b. General health sciences:

- Anatomy and physiology
- Pathology
- Bacteriology, virology and parasitology
- Biophysics, biochemistry and radiology
- Dietetics
- Hygiene:
 - preventive medicine
 - health education
- Pharmacology

c. Social sciences:

- Sociology
- Psychology
- Principles of administration and management
- Principles of teaching
- Social and health legislation
- Legal aspects of nursing

d. Science and technology:

- e-health

B. Clinical instruction

— Nursing in relation to:

- general and specialist medicine
- general and specialist surgery
- childcare and paediatrics
- maternity care
- mental health and psychiatry
- care of the elderly and geriatrics
- nursing care in community settings
- person-centred approach

— Science and technology:

- e-health

One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.

Theoretical instruction must be weighted and coordinated with clinical instruction in such a way that the knowledge and skills referred to in this Annex can be acquired in an adequate fashion.;

(2) point 5.3.1 is replaced by the following:

‘5.3.1 Study programme for dental practitioners

The programme of studies leading to evidence of formal qualifications in dentistry shall include at least the following subjects. One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.

A. Basic subjects

- Chemistry
- Physics
- Biology, genetics and regenerative medicine

B. Medico-biological subjects and general medical subjects

- Anatomy
- Embryology
- Histology, including cytology
- Physiology
- Biochemistry (or physiological chemistry)
- Pathological anatomy
- General pathology
- Pharmacology

- Microbiology
- Hygiene
- Preventive medicine and dental public health
- Radiology
- Physiotherapy
- General surgery
- General medicine, including paediatrics
- Oto-rhino-laryngology
- Dermato-venereology
- General psychology — psychopathology — neuropathology
- Anaesthetics
- Immunology

C. Subjects directly related to dentistry

- Prosthodontics
- Dental materials and equipment
- Conservative dentistry
- Preventive dentistry
- Anaesthetics and sedation
- Special surgery
- Special pathology
- Clinical practice
- Paedodontics
- Orthodontics
- Periodontics
- Dental radiology
- Dental occlusion and function of the jaw
- Practice management, professionalism, ethics and legislation
- Social aspects of dental practice
- Gerodontology
- Oral implantology
- Interprofessional collaborative care
- Digital technology in dentistry’;

(3) point 5.6.1 is replaced by the following:

'5.6.1 Course of training for pharmacists

- Plant and animal biology
- Physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Anatomy, physiology, pathology and pathophysiology; medical terminology
- Microbiology
- Pharmacology and pharmacotherapy
- Pharmaceutical technology
- Biopharmaceutical technology
- Toxicology
- Pharmacognosy
- Legislation and, where appropriate, professional ethics
- Genetics and pharmacogenomics
- Immunology
- Clinical pharmacy
- Pharmaceutical care
- Social pharmacy
- Public health, including epidemiology
- Pharmacy practice
- Pharmacoeconomics

The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.'
