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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED DIRECTIVE (EU) .../... of 4.3.2024 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

Delegations will find attached document C(2024) 1319 final.

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Brussels, 4.3.2024
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COMMISSION DELEGATED DIRECTIVE (EU) .../...

of 4.3.2024

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications¹ ('the Professional Qualifications Directive') consolidated harmonised minimum training requirements for a number of professions that were previously set out in several separate directives. Minimum requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist were set out in directives adopted between 1977 and 1985².

In its 2011 Green Paper on the modernisation of the Professional Qualifications Directive³, the European Commission acknowledged the need to modernise harmonised minimum training requirements in different phases. In the context of the last revision of the Professional Qualifications Directive through Directive 2013/55/EU⁴, national authorities, training institutions and professional organisations indicated that the professions covered by the Title III of Chapter III of the Professional Qualifications Directive, including nurse responsible for general care, dental practitioner and pharmacist, have significantly evolved since their minimum training requirements were harmonised.

While certain changes to the minimum harmonised training requirements were made by Directive 2013/55/EU, no comprehensive review was carried out in relation to the minimum requirements for the professions of nurse responsible for general care, dental practitioner and pharmacist, in particular with regard to:

- training programmes listed in points 5.2.1, 5.3.1 and 5.6.1 of Annex V to the Professional Qualifications Directive;
- the list of minimum knowledge and skills to be acquired during training (Articles 31(6), 34(3) and 44(3) of the Professional Qualifications Directive).

¹ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255 30.9.2005, p. 22).

² Council Directive 77/452/EEC of 27 June 1977 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of nurses responsible for general care, including measures to facilitate the effective exercise of this right of establishment and freedom to provide services (OJ L 176, 15/07/1977, p. 1); Council Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (OJ L 233, 24.8.1978, p. 1); Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (OJ L 253, 24.9.1985, p. 37).

³ Green Paper, Modernising the Professional Qualifications Directive, COM(2011)367 final.

⁴ 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 (OJ L 354, 28.12.2013, p. 132).

Instead, Directive 2013/55/EU provided the Commission with delegated powers to introduce updates, if necessary, to the minimum training requirements in order to adapt them to generally acknowledged scientific and technical progress:

- Article 21(6) of the Professional Qualifications Directive empowers the Commission to adopt delegated acts to update the provisions in the Professional Qualifications Directive on knowledge and skills referred to in Articles 31(6), 34(3) and 44(3);
- Articles 31(2), 34(2) and 44(2) of the Professional Qualifications Directive empower the Commission to update training programmes included in points 5.2.1, 5.3.1 and 5.6.1 of Annex V to the Professional Qualifications Directive.

This delegated act is based on all above-mentioned empowerments. The reason for including them in one delegated act is that they all enable the update of the minimum training requirements for the professions covered by Chapter III of Title III of the Professional Qualifications Directive.

The Commission has assessed whether the minimum training requirements laid down in the Professional Qualifications Directive for the professions of nurse responsible for general care, dental practitioner and pharmacist require an update in light of generally acknowledged scientific and technical progress. To assist the Commission in its assessment, three studies were commissioned. They aim to explore the developments of training requirements for these professions in all Member States and European Free Trade Association States (EFTA States).⁵ For that purpose, data was collected at EU and national level through desk research and targeted stakeholder consultations. The data collection focused on the following developments in training requirements at national level:

- scientific and technical advancements affecting the professions of nurse responsible for general care, dental practitioner and pharmacist;
- training programmes as well as knowledge and skills that go beyond the minimum training requirements laid down in the Professional Qualifications Directive and that reflect any adaptation to scientific and technical advancements.

Moreover, a comparative assessment of the data collected was carried out. It focused on developments in and commonalities of training requirements across all 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 observed in at least 16 EU Member States or EFTA States. The results of these studies were presented to relevant stakeholders during workshops and meetings of the group of coordinators for the recognition of professional qualifications.⁶ Based on the feedback received by relevant

⁵ 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, <https://data.europa.eu/doi/10.2873/30>; 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, <https://data.europa.eu/doi/10.2873/2748>; Mapping and assessment of developments for sectoral professions under Directive 2005/36/EC – The profession of pharmacist, Publications Office of the European Union, 2022, <https://data.europa.eu/doi/10.2873/077373>.

⁶ Commission Decision of 19 March 2007 setting up the group of coordinators for the recognition of professional qualification (OJ L 79, 20.3.2007, p. 38).

stakeholders, the conclusions of the studies were drafted, suggesting updates to minimum training requirements laid down in the Professional Qualifications Directive as regards training programmes as well as knowledge and skills.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

As per the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁷, the Commission consulted on the draft delegated directive in writing with the experts from the group of coordinators for the recognition of professional qualifications between 30 October 2023 and 20 November 2023 and at the online meeting of the group of coordinators on 14 December 2023.

Following the consultation with the group of coordinators, the following changes were made to this draft delegated directive:

- the period for Member States to transpose this directive into national law has been set at 2 years;
- the amendments to Directive 2005/36/EC included in the draft delegated directive have been presented in a consolidated manner;
- as regards the profession of nurse responsible for general care, the proposed amendment of Article 31(6) point (g), ‘comprehensive knowledge of the technical innovations related to healthcare and nursing methods’, has been changed to ‘knowledge of the technical innovations related to healthcare and nursing methods’;
- as regards the profession of pharmacist:
 - in Annex V point 5.6.1: ‘Biopharmaceutical technology’ has been made a separate training subject, distinct from ‘Pharmaceutical technology’;
 - in Annex V point 5.6.1: the training subject ‘Health economics’ has been deleted.

In view of comments and questions addressed to it during that consultation, the Commission recalls that, in line with the nature of the act, when transposing the minimum training requirements set out in Directive 2005/36/EC into national law, Member States can choose the form and methods of transposition as long as the objectives are attained and it is clear from the national legal framework that there is an obligation on training institutions to implement each minimum training requirement. In addition, the Commission notes that nurses responsible for general care, dental practitioners and pharmacists who are nationals of a Member State and obtained a professional qualification listed in points 5.2.2, 5.3.3 or 5.6.2 of Annex V to Directive 2005/36/EC after following a course of training that commenced before the end of the transposition period set out in this delegated directive and that satisfied the minimum training requirements under the Directive applicable when the training began, benefit from automatic recognition of their professional qualifications pursuant to Article 21(1) of Directive 2005/36/EC.

⁷ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

Furthermore, the draft delegated directive was subject to public feedback on the Commission's 'Have Your Say' platform between 15 January 2024 and 12 February 2024. The majority of the feedback supported updating the minimum training requirements. In addition, numerous reactions also contained proposals for additional changes to the minimum training requirements that were not identified as generally acknowledged scientific and technical progress by the results of the aforementioned studies, or that go beyond the scope of the European Commission's delegated powers at the basis of this delegated directive.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The empowerment to adopt this Delegated Act is provided for in Articles 21(6), 31(2), 34(2) and 44(2) of the Professional Qualifications Directive.

Article 1 of this Delegated Act lays down the amendments to the Professional Qualifications Directive with regard to knowledge and skills required for the three professions of nurse responsible for general care, dental practitioner and pharmacist. Article 1 also refers to the Annex in which amendments to the minimum training programmes for these professions are set out.

Article 2 sets the period for transposition of the Delegated Act and the requirements for Member States to communicate measures that they adopt to the Commission.

Article 3 specifies the date of entry into force of the Delegated Act.

Article 4 specifies the addressees of the Delegated Act.

Commission Delegated Directive (EU) .../... of 4.3.2024 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 qualifications¹, 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/EC², 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 Council³, 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

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>).

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.
- (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 care⁴ 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.

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.

- (11) The study on dental practitioners⁵ 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 pharmacists⁶ 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.
- (13) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents⁷, 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

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.

⁷ OJ C 369, 17.12.2011, p. 14.

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;
- (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 ... [*OP please insert the date = 2 years from the date of adoption of this Directive*] 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, 4.3.2024

For the Commission
The President
Ursula VON DER LEYEN