#### STATUTORY INSTRUMENTS

## 2016 No. 1030

# HEALTH CARE AND ASSOCIATED PROFESSIONS PROFESSIONAL QUALIFICATIONS

## The European Qualifications (Health and Social Care Professions) Regulations 2016

25th October 2016 Made Laid before Parliament 28th October 2016 Coming into force -18th November 2016

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The Secretary of State is designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to measures relating to access to, the training for, the pursuit of, and the award of qualifications in the professions of medicine, pharmacy, dentistry, nursing and midwifery, and their specialities, in certain other health care professions and in the profession of social worker, and in relation to the recognition of higher education diplomas, formal qualifications, or experience in the occupation, required for the pursuit of professions or occupations.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears expedient to the Secretary of State for certain references to provisions of European Union instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972, as read with paragraph 1A of Schedule 2 to that  $Act(\mathbf{c})$ .

<sup>(</sup>a) S.I. 1995/3207; 2002/248; and 2003/2901. There are amendments to S.I. 2002/248 and 2003/2901, but these are not relevant to these Regulations. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scotlish Ministers of functions in relation to implementing obligations under European Union law in relation to certain matters by virtue of section 53 of that Act, these functions continue to be exercisable by the Secretary of State as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972 (c.68).

<sup>(</sup>b) Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).

<sup>(</sup>c) Paragraph 1A was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and was amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 and by S.I. 2007/1388.

## PART 1

## PRELIMINARY MATTERS

#### Citation and commencement

**1.** These Regulations may be cited as the European Qualifications (Health and Social Care Professions) Regulations 2016 and come into force on 18th November 2016.

#### **Extent**

2. The extent of any amendment made by these Regulations is the same as that of the enactment amended.

## PART 2

## MEDICAL PRACTITIONERS

#### CHAPTER 1

#### AMENDMENT OF THE MEDICAL ACT 1983

## Introductory

3. The Medical Act 1983(a) is amended in accordance with this Chapter.

#### **Insertion of section 10B**

**4.** After section 10A (programmes for provisionally registered doctors)(**b**), insert—

## "Professional traineeships carried out in other relevant European States, etc.

- **10B.**—(1) If an acceptable programme for provisionally registered doctors includes a requirement to carry out a professional traineeship of a particular standard, a professional traineeship of an equivalent standard that has been carried out in a relevant European State other than the United Kingdom, by a person who is a national of a relevant European State and who holds a primary United Kingdom qualification, is treated as meeting that requirement.
- (2) The General Council must publish guidelines on the organisation and recognition of professional traineeships carried out in relevant European States (including, in particular, guidelines on the role of the supervisor of the professional traineeship).
  - (3) Any person who—
    - (a) is not a national of a relevant European State; but
    - (b) is, by virtue of any enforceable EU right, entitled to be treated, for the purposes of access to and the practice of the medical profession, no less favourably than a national of such a State,

must be treated for the purposes of subsection (1) as if the person were such a national.".

<sup>(</sup>a) c. 54.

<sup>(</sup>**b**) Section 10A was inserted by S.I. 2006/1914.

#### **Amendment of section 14**

- 5. In section 14 (alternative requirements as to experience in certain cases)(a), at the end insert—
  - "(4) Subsection (5) applies if—
    - (a) a person within subsection (2)(b) who is a national of a relevant European State makes an application under subsection (1); and
    - (b) the person has carried out a professional traineeship, all or part of which was carried out in a third country.
  - (5) The General Council must take the professional traineeship into account in exercising its functions under subsection (1).
  - (6) The General Council must publish guidelines on the organisation and recognition of professional traineeships carried out in third countries (including, in particular, guidelines on the role of the supervisor of the professional traineeship).
    - (7) Any person who—
      - (a) is not a national of a relevant European State; but
      - (b) is, by virtue of any enforceable EU right, entitled to be treated, for the purposes of access to and the practice of the medical profession, no less favourably than a national of such a State,

must be treated for the purposes of subsections (4) and (5) as if the person were such a national.".

#### Amendment of section 14A

- **6.**—(1) Section 14A (full registration of EEA nationals etc without certain acquired rights certificates)(**b**) is amended as follows.
  - (2) In subsection (1)(a), for "3(9)(a)" substitute "3(8)(a)".
  - (3) In subsection (1)(b)—
    - (a) for "20 to 26" substitute "27 to 34";
    - (b) for "3(4)" substitute "3(5)".

#### Amendment of section 19A

- 7.—(1) Section 19A (full registration of EEA nationals etc by virtue of overseas qualifications accepted by a relevant European State other than the United Kingdom)(c) is amended as follows.
  - (2) In paragraph (a), for "3(9)(e)" substitute "3(8)(e)";
  - (3) In paragraph (b)—
    - (a) for "20 to 26" substitute "27 to 34";
    - (b) for "3(4)" substitute "3(5)".

#### Amendment of section 40

**8.**—(1) Section 40 (appeals by persons subject to decisions by Tribunals)(**d**) is amended as follows.

<sup>(</sup>a) Section 14 was amended by S.I. 1996/1591, 2006/1914 and 2007/3101.

<sup>(</sup>b) Section 14A was inserted by S.I. 2007/3101 and amended by 2011/1043.

<sup>(</sup>c) Section 19A was inserted by S.I. 2007/3101.

<sup>(</sup>d) Section 40 was amended by S.I. 2006/1914 (which, in particular, inserted subsections (1A) and (4A)), 2007/3101 and 2015/794 (which, in particular, substituted the heading to section 40). There are other amendments which are not relevant to these Regulations.

- (2) After subsection (1A), insert—
  - "(1B) A decision of the General Council under regulation 67 of the General Systems Regulations to send an alert about a person is also an appealable decision for the purposes of this section."
- (3) In subsection (4A), after "(1A)" insert "or (1B)".
- (4) In subsection (8)(b), after "against", insert "or, in the case of an appeal from a decision falling within subsection (1B), direct that the alert be withdrawn or amended".
  - (5) In the heading, omit "by persons subject to decisions by Tribunals".

#### **Amendment of section 55**

- **9.**—(1) Section 55(1) (interpretation)(**a**) is amended as follows.
- (2) For the definition of "the General Systems Regulations" (b), substitute—

"the General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

(3) In the appropriate places, insert—

""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";

""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";

""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;";

""professional traineeship" means a period of professional practice, carried out under supervision, that—

- (a) constitutes a condition for access to the medical profession in the country in which it is carried out; and
- (b) takes place during or after completion of a course of education leading to an educational qualification pursued for the purpose of entry to that profession;";

## Amendment of Schedule 2A

- **10.**—(1) Schedule 2A (visiting medical practitioners from relevant European States)(c) is amended as follows.
  - (2) In paragraph 4(b)—
    - (a) for "3(9)(a), (c) or (e)" substitute "3(8)(a), (c) or (e)";
    - (b) for "14 to 16" substitute "19 to 23".
  - (3) In paragraph 5—
    - (a) in sub-paragraph (2)(a)—
      - (i) in sub-paragraph (i), omit the "and" at the end;
      - (ii) after sub-paragraph (ii), insert—

<sup>&</sup>quot;"third country" means a country other than a relevant European State;".

<sup>(</sup>a) Section 55 was amended by section 99 of, and Schedule 7 to, the Health and Social Care Act 2008 (c.14) and by S.I. 1996/1591, 2000/3041, 2002/3135, 2006/1914, 2007/3101, 2008/1774, 2010/234, 2011/1043, 2014/1101 and 2015/794.

<sup>(</sup>b) The definition of "the General Systems Regulations" was inserted by S.I. 2007/3101.

<sup>(</sup>c) Schedule 2A was inserted by S.I. 2007/3101.

- "(iii) confirms that the practitioner does not have a criminal conviction; and
- (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a medical practitioner;";
- (b) after sub-paragraph (2)(a), insert—
  - "(aa) a written declaration as to whether the practitioner has the necessary knowledge of English;";
- (c) in sub-paragraph (3), after "(2)(a)" insert "or (aa)".
- (4) In paragraph 6(3)—
  - (a) for "3(9)(a), (c) or (e)" substitute "3(8)(a), (c) or (e)";
  - (b) for "14 to 16" substitute "19 to 23".
- (5) In paragraph 8(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a medical professional".

#### Amendment of Schedule 4A

- 11.—(1) Schedule 4A (Directive 2005/36: functions of the General Council under section 49B(3)) (a) is amended as follows.
  - (2) Before the entry relating to article 7(2)(b) insert—

"Article 4f

Considering applications for partial access to the medical profession under regulations 10 and 11 of the General Systems Regulations."

- (3) In the entry relating to article 8(1)—
  - (a) for "Receiving", substitute "In the event of justified doubts, receiving"; and
  - (b) after paragraph (c), insert—

"Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.".

(4) After the entry relating to article 50(3), insert—

"Article 50(3a) In the event of justified doubts, seeking confirmation from, or

providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the medical profession as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's professional activities.

Article 50(3b) Ensuring that the exchange of information under article 50 of the

Directive with other competent authorities takes place through the IMI.

Article 53 Ensuring that any language controls imposed on a medical practitioner

are compliant with article 53 of the Directive.

Article 55a When considering an application for registration as a fully registered

practitioner, ensuring that in respect of professional traineeships—
(a) traineeships undertaken in a relevant European State are recognised

in accordance with published guidelines;

(b) traineeships undertaken in a third country are taken into account."

(5) In the entry relating to article 56(2), after paragraph (c), insert—

"Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI.".

<sup>(</sup>a) Schedule 4A was inserted by S.I. 2007/3101.

(6) After the entry rela	ating to article 56(2), insert—
"Article 56(2a)	Ensuring that the exchange of information carried out in accordance with article 56(2) of the Directive takes place through the IMI.
Article 56a(1) and (2)	Informing all other competent authorities, by way of an alert through the IMI, about a medical practitioner whose professional activities have been restricted or prohibited, even temporarily, within three days from the date of adoption of the decision; ensuring the information provided is limited to the information referred to in article 56a(2) of the
Article 56a(3)	Directive.  Informing all other competent authorities, by way of an alert through
	the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications, within three days from the date of the finding.
Article 56a(4)	Ensuring that the processing of personal data for the purposes of the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC.
Article 56a(5)	Informing all other competent authorities through the IMI without delay when—
	(a) a prohibition or a restriction referred to in article 56a(1) of the Directive has expired;
	(b) there is a change to the prohibition or restriction period notified under article 56a(2) of the Directive.
Article 56a(6)	Notifying the medical practitioner, in respect of whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the practitioner—
	(a) is the subject of an alert sent under article 56a(1) or (3) of the Directive;
	(b) has the right to appeal the decision or to apply for rectification of the decision;
	(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.
	Informing competent authorities, where applicable, that an alert is subject to appeal proceedings by the practitioner.
Article 56a(7)	Ensuring that an alert made under article 56a(1) of the Directive is deleted from the IMI within three days of—  (a) the date of adoption of the revoking decision; or  (b) the expiry of the prohibition or restriction referred to in that article.
Article 57a(1)	Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications of a medical practitioner may be easily completed by the applicant remotely and by electronic means."

## CHAPTER 2

# AMENDMENT OF THE POSTGRADUATE MEDICAL EDUCATION AND TRAINING ORDER OF COUNCIL 2010

## Introductory

12. The Postgraduate Medical Education and Training Order of Council  $2010(\mathbf{a})$  is amended in accordance with this Chapter.

<sup>(</sup>a) S.I. 2010/473.

#### Amendment of article 5

- **13.**—(1) Article 5 (general systems general practitioners eligible for entry in the general practitioner register) is amended as follows.
  - (2) In paragraph (a), for "3(9)(e)" substitute "3(8)(e)".
  - (3) In paragraph (b)—
    - (a) for "20 to 26" substitute "27 to 34";
    - (b) for "3(4)" substitute "3(5)".

## Amendment of article 9

- **14.**—(1) Article 9 (general systems specialists eligible for entry in the specialist register) is amended as follows.
  - (2) In paragraph (a), for "3(9)(a), (c) or (e)" substitute "3(8)(a), (c) or (e)".
  - (3) In paragraph (b)—
    - (a) for "20 to 26" substitute "27 to 34";
    - (b) for "3(4)" substitute "3(5)".

#### Amendment of article 10

- **15.**—(1) Article 10 (recognised specialist qualifications granted outside the United Kingdom) is amended as follows.
  - (2) In paragraph (1)(f)(iii), omit the "and" at the end.
  - (3) After paragraph (1)(g) (after the table), insert—
    - "(h) a specialist qualification listed in Annex V, points 5.1.2 and 5.1.3 of the Directive—
      - (i) which was awarded in Italy to doctors who started their specialist training after 31st December 1983 and before 1st January 1991 (even if the training concerned did not satisfy all the training requirements of article 25 of the Directive);
      - (ii) which was awarded in a recognised specialty; and
      - (iii) where evidence of the qualification is accompanied by a certificate of a competent authority in Italy stating that the holder has effectively and lawfully been engaged, in Italy, in the activities of a medical specialist in that specialty for at least seven consecutive years during the ten years preceding the date of the certificate."

#### Insertion of articles 12 and 13

**16.** After article 11, insert—

#### "Partial exemption

- 12.—(1) The Registrar may exempt a person from a requirement to complete part ("the relevant part") of a specialist training course in the United Kingdom if the conditions in paragraph (2) are satisfied.
  - (2) The conditions are that—
    - (a) the person has already completed the equivalent of the relevant part, whilst completing a specialist training course in a relevant European State and in respect of which the person obtained a qualification; and
    - (b) the relevant part does not equate to more than half of the minimum duration of the specialist training course in respect of which the exemption is to apply.

(3) In this article, "specialist training course" means a course listed in Annex V, point 5.1.3 of the Directive.

#### Review

- **13.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to this Order by the European Qualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

## PART 3

# PHARMACISTS AND PHARMACY TECHNICIANS CHAPTER 1

#### AMENDMENT OF THE PHARMACY (NORTHERN IRELAND) ORDER 1976

#### Introductory

17. The Pharmacy (Northern Ireland) Order  $1976(\mathbf{a})$  is amended in accordance with this Chapter.

#### Amendment of article 2

- **18.**—(1) Article 2(2) (interpretation)(**b**) is amended as follows.
- (2) For the definition of "General Systems Regulations" substitute—
  - ""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);"(c).
- (3) In the appropriate places, insert—
  - ""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";
  - ""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12th July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";
  - ""European professional card" has the meaning given in the Directive;";
  - ""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;";
  - ""IMI file" means a secure personal account in the IMI that is created in relation to an applicant for a European professional card by means of an online tool provided by the European Commission;";
  - ""professional traineeship" means a period of professional practice, carried out under supervision, that—

<sup>(</sup>a) S.I. 1976/1213 (N.I. 22).

<sup>(</sup>b) Article 2 was amended by S.R. (N.I.) 2008 No. 192 and 2012 No. 308, and by S.I. 2012/1916 and 2015/806.

<sup>(</sup>c) The definition of "General Systems Regulations" was inserted by S.R. (N.I.) 2008 No. 192.

- (a) constitutes a condition for access to the profession of pharmacy in the country in which it is carried out; and
- (b) takes place during or after completion of a course of education leading to an educational qualification pursued for the purpose of entry to that profession;";

""third country" means a country other than a relevant European State.".

#### Amendment of article 8

- 19.—(1) Article 8 (qualifications for registration)(a) is amended as follows.
- (2) In paragraph (2)(c)(ii)(aa), for "3(9)(a) or (e)" substitute "3(8)(a) or (e)".
- (3) In paragraph (2)(c)(ii)(bb)—
  - (a) for "20 to 26" substitute "27 to 34";
  - (b) for "3(4)" substitute "3(5)".

#### Amendment of article 8A

**20.** In article 8A (registration by virtue of appropriate European diploma)(**b**), in paragraph (2), for "Subject to paragraph (8)" substitute "Subject to paragraph (7)".

#### **Insertion of articles 8C and 8D**

**21.** After article 8B (visiting pharmaceutical chemist from a relevant European State)(c), insert—

#### "Professional traineeships carried out in other relevant European States, etc.

- **8C.**—(1) If a person is required to carry out a professional traineeship of a particular standard in order to be appropriately qualified to be registered in the register of pharmaceutical chemists, a professional traineeship of an equivalent standard which has been carried out by a person whose home Member State is the United Kingdom and which satisfies the conditions in paragraph (2) is treated as meeting that requirement.
  - (2) The conditions are that—
    - (a) at least three quarters of the time of which the professional traineeship consisted, or such lesser proportion as the Society may consider appropriate in any particular case, was spent in the United Kingdom; and
    - (b) the remaining time of which the professional traineeship consisted was spent in another relevant European State.
  - (3) Paragraph (4) applies if—
    - (a) a person whose home Member State is the United Kingdom applies to the registrar to be registered as a pharmaceutical chemist; and
    - (b) the person has carried out a professional traineeship, all or part of which was carried out in a third country.
- (4) The registrar must take the professional traineeship into account when considering whether the person satisfies any requirement as to the qualifications needed in order to be registered in the register of pharmaceutical chemists which includes a requirement to carry out a professional traineeship in the United Kingdom.
- (5) The Society must publish guidelines on the organisation and recognition of professional traineeships carried out in relevant European States and third countries

<sup>(</sup>a) Article 8(2)(c) was substituted by S.R. (N.I.) 2008 No. 192.

<sup>(</sup>a) Article 8A was inserted by S.R. (N.I.) 1987 No. 457 and amended by 1996 No. 393 and 2008 No. 192.

<sup>(</sup>c) Article 8B was inserted by S.R. (N.I.) 2008 No. 192.

(including, in particular, guidelines on the role of the supervisor of the professional traineeship).

(6) In this Article, "home Member State" has the meaning given in article 1 of the Directive.

## European professional card

- **8D.**—(1) Schedule 2C (Directive 2005/36/EC: European professional card) has effect.
- (2) The Society may charge a reasonable fee to cover the costs of processing an application for or in relation to a European professional card under Schedule 2C.
- (3) The Council must determine, and the Department must approve, the amount which the Society may charge under paragraph (2).".

#### Insertion of articles 11ZZA and 11ZZB

22. After article 11 (evidence of qualification to be registered), insert(a)—

## "Appeals: decisions in relation to alerts and European professional cards

**11ZZA.** The following are appealable to the Council—

- (a) a decision of the Society under regulation 67 of the General Systems Regulations to send an alert about a person;
- (b) a decision of the Society to revoke, or not to issue, extend or vary, a European professional card under Schedule 2C or Part 4 of the General Systems Regulations;
- (c) a failure by the Society to make a decision in relation to a European professional card within the time limit under paragraph 10(4) or 12(4) of Schedule 2C or regulation 51(1) or 56(1) of the General Systems Regulations.

## Appeals to the Council under Article 11ZZA

- **11ZZB.**—(1) A person in respect of whom a decision falling within Article 11ZZA(a) or (b) has been made may appeal to the Council by giving notice of appeal to the registrar within 28 days beginning with and including the date on which the Society gave notice of its decision to the person.
- (2) A person in respect of whom the Society has failed to make a decision falling within Article 11ZZA(c) may appeal to the Council by giving notice of appeal to the registrar within 28 days beginning with and including the date by which the Society was required to have given notice of its decision to the person.
- (3) The registrar may, by authorisation in writing, extend the time for giving notice of appeal under paragraph (1) or (2) by up to 14 days.
  - (4) Having considered the appeal, the Council may—
    - (a) dismiss the appeal;
    - (b) allow the appeal and quash the decision appealed against or, in the case of an appeal against a decision falling within Article 11ZZA(a), direct that the alert be withdrawn or amended:
    - (c) substitute for the decision appealed against any decision or other decision that could have been taken by the decision maker or, in the case of an appeal under paragraph (2), enter any decision which could have been taken by the Society; or
    - (d) remit or refer the case to the Society or the registrar for disposal of the matter in accordance with the Council's directions.

 $<sup>\</sup>textbf{(a)} \quad \text{Article 11 was amended by S.R. (N.I.) 2008 No. 192 and 2012 No. 308; article 11ZA was inserted by S.I. 2015/806.$ 

- (5) The Council must, as soon as reasonably practicable, send to the appellant a statement in writing giving the appellant notice of the Council's decision and the reasons for it.
- (6) Subject to paragraph (7), the Council must, as soon as reasonably practicable, publish, in such manner as it sees fit, its decision and the reasons for it.
- (7) If the Council has allowed the appeal, or has taken a decision or issued a direction that has the effect of allowing the appeal, it is not required to publish its decision or direction, and the reasons for it, unless the appellant so requests."

#### **Insertion of article 22A**

**23.** In Part 5 (miscellaneous), before article 23 (dispensing, etc., in public institutions)(**a**), insert—

## "The Directive: functions of competent authority, etc.

- **22A.**—(1) The Society is designated as the competent authority in Northern Ireland for the purposes of the Directive so far as it relates to the profession of pharmacy.
- (2) The Society must in Northern Ireland carry out (in particular) the functions specified in Schedule 2D.
- (3) The Society is designated as the competent authority in Northern Ireland for the award of evidence of formal qualifications in pharmacy listed in relation to the United Kingdom in Annex V, point 5.6.2 of the Directive.
- (4) The Department may give directions to the Society as to matters of administration in connection with the functions of the Society specified in Schedule 2D.
  - (5) The Society must comply with a direction given under paragraph (4).
  - (6) In Schedule 2D—
    - (a) "NI pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by the Society;
    - (b) "non-UK pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by a competent authority of a relevant European State other than the United Kingdom;
    - (c) references in that Schedule to a pharmacist include a pharmaceutical chemist.".

#### **Amendment of Schedule 2B**

- **24.**—(1) Schedule 2B (visiting pharmaceutical chemist from a relevant European State)(b) is amended as follows.
  - (2) For paragraph 1, substitute—
    - "1. This Schedule applies to a person who—
      - (a) is an exempt person who is lawfully established as a pharmacist in a relevant European State other than the United Kingdom; and
      - (b) is not a person to whom paragraph 15 of Schedule 2C (European professional card and entitlement to registration: provision of occasional pharmacy services) to this Order or paragraph 15 of Schedule 2A (European professional card and entitlement to registration: provision of occasional pharmacy services) to the Pharmacy Order 2010 (S.I. 2010/231) applies.".
  - (3) In paragraph 4(b)—
    - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e)";

<sup>(</sup>a) Article 22 was originally in Part 4; articles 21 and 22 were revoked by S.R. (N.I.) 2012 No. 308.

<sup>(</sup>b) Schedule 2B was inserted by S.R. (N.I.) 2008 No. 192.

- (b) for "14 to 16" substitute "19 to 23";
- (4) In paragraph 5—
  - (a) in sub-paragraph (2)(a)—
    - (i) in sub-paragraph (i), omit the "and" at the end;
    - (ii) after sub-paragraph (ii), insert—
      - "(iii) confirms that the practitioner does not have a criminal conviction; and
      - (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a pharmacist;";
  - (b) after sub-paragraph (2)(a), insert—
    - "(aa) a written declaration as to whether the practitioner has the necessary knowledge of English;";
  - (c) in sub-paragraph (3), after "(2)(a)" insert "or (aa)".
- (5) After paragraph 5, insert—

### "First provision of services: visiting practitioners from Great Britain

- **5A.**—(1) The registrar must treat a visiting practitioner who—
  - (a) applies to be registered in the register mentioned in Article 6(1)(d) as a visiting practitioner; and
  - (b) is entered in Part 4 of the register maintained under article 19 of the Pharmacy Order 2010 relating to pharmacists who are visiting practitioners to Great Britain,

as complying with the requirements of paragraph 5.

- (2) The registrar may require the visiting practitioner to provide additional information concerning his or her professional qualifications as a result of differences in the way that the profession is regulated in different parts of the United Kingdom.
- (3) Sub-paragraph (1) does not apply if the registrar has required the visiting practitioner to provide information under sub-paragraph (2) and the visiting practitioner has not done so.".
- (6) In paragraph 6(2)—
  - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e);
  - (b) for "14 to 16" substitute "19 to 23".
- (7) In paragraph 8(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a pharmacist".

#### Insertion of Schedules 2C and 2D

25. After Schedule 2B insert—

## Directive 2005/36/EC: European professional card

## PART 1

#### General

#### Introductory

**1.** This Schedule supplements the rights and obligations set out in the Implementing Regulation 2015.

## Interpretation

#### 2. In this Schedule—

"automatically recognised pharmacist" means a person who is entitled to have his or her qualifications as a pharmacist automatically recognised under articles 21, 23, 49a or 49b of the Directive:

"disqualifying decision" means a decision made by a competent authority or a judicial authority in a person's home State or host State that has the effect that—

- (a) the person ceases to be registered or otherwise officially recognised as a pharmacist in that State; or
- (b) the person is prohibited, permanently or temporarily, from practising as a pharmacist in that State;

"EPC applicant" means a person making, or who has made, an EPC application;

"EPC application" means an application for a European professional card made by a person who is seeking to practise as an automatically recognised pharmacist;

"EPC holder" means a person who holds a valid European professional card as a result of an EPC application;

"home State" means the relevant European State specified by an EPC applicant in his or her EPC application in accordance with article 4 of the Implementing Regulation 2015;

"host State" means the relevant European State in which an EPC applicant seeks to practise as a pharmacist;

"Implementing Regulation 2015" means Commission Implementing Regulation (EU) No 983 of 2015 on the procedure for issuance of the European professional card and the application of the alert mechanism pursuant to the Directive;

"missing document" means a document which an EPC applicant was required to provide with the EPC application but which the EPC applicant has not provided;

"occasional pharmacy services" means the provision of services as a pharmacist on a temporary and occasional basis; and

references to a pharmacist include a pharmaceutical chemist.

## PART 2

General functions of the Society in relation to European professional cards

## Society not to request resubmission of valid documents

**3.** If a person ("P") who has already made an application for or in relation to a European professional card makes a subsequent or further application for or in relation to a European

professional card, the Society may not request resubmission of documents that are contained in P's IMI file and which are still valid for the purposes of processing P's subsequent or further application.

## Power to revoke a European professional card

- **4.**—(1) The Society may revoke a European professional card issued under this Schedule if it appears to the Society that the person ("P") to whom the card was issued is not entitled to hold the card.
- (2) P is not entitled to hold a European professional card if, in particular, P is subject to a disqualifying decision.

## Rectification of the European professional card or the IMI file

- **5.**—(1) If an automatically recognised pharmacist ("P") holds a European professional card issued by the Society, P may, at any time, make a written request to the Society to rectify inaccurate or incomplete data in P's IMI file or to delete or block P's IMI file if it contains inaccurate or incomplete data.
- (2) If the Society is satisfied that the data in P's IMI file is inaccurate or incomplete, the Society must comply with a request by P under sub-paragraph (1).
  - (3) The Society must notify P of P's right under sub-paragraph (1)—
    - (a) at the time P's European professional card is issued;
    - (b) within the period ending two years after the date on which the European professional card was issued; and
    - (c) subsequently at intervals not exceeding two years from the date of the previous notification.
- (4) A notification under sub-paragraph (3)(b) or (c) must be sent to P by means of an automatic reminder sent through the IMI.
- (5) The Society must not charge P a fee in relation to the making of a written request under sub-paragraph (1) or in relation to complying with, or responding to, such a request.
  - (6) If—
    - (a) P's European professional card was issued for the purposes of establishment;
    - (b) Pasks the Society to delete P's IMI file; and
    - (c) P's host State is the United Kingdom,

the Society must provide P with evidence confirming that the Society recognises P's professional qualifications.

## Duty to give reasons and to notify of right of appeal

**6.** If the Society refuses to issue, extend or vary, or decides to revoke, a European professional card under this Schedule, the Society must notify the EPC applicant or the EPC holder of the reasons for that decision and of his or her right of appeal under Article 11ZZB.

#### Updating the IMI file: disciplinary action or criminal sanctions

- 7.—(1) This paragraph applies if a person ("P")—
  - (a) makes an EPC application to the Society; or
  - (b) is an EPC holder and P's European professional card was issued by the Society.
- (2) The Society must update P's IMI file in accordance with sub-paragraphs (3) and (4) in a timely manner.

- (3) The Society must add to P's IMI file information, regarding disciplinary action or criminal sanctions, which—
  - (a) relates to a prohibition or restriction on P's entitlement to practise as a pharmacist; or
  - (b) has consequences for the pursuit of any activities by P, in P's capacity as a pharmacist.
- (4) The Society must delete from P's IMI file information regarding disciplinary action or criminal sanctions that is no longer required.
- (5) The Society must immediately inform P and the competent authorities of other relevant European States that have access to P's IMI file of any update under this paragraph.
- (6) The information that may be added or deleted under this paragraph is limited to details of—
  - (a) P's identity;
  - (b) information about the national authority or court which has made a decision on a restriction or prohibition applying to P;
  - (c) the scope of the restriction or prohibition; and
  - (d) the period for which the restriction or prohibition applies.

#### Access to data

- **8.**—(1) The Society may access information on the IMI file of an EPC applicant or an EPC holder, in accordance with Directive 95/46/EC, only if the United Kingdom is the home State or the host State of the applicant or the holder.
- (2) The Society must provide an EPC applicant or an EPC holder with information on the content of his or her IMI file on request.

#### **Processing data**

- **9.**—(1) The Society may process personal data to which it has access under paragraph 8—
  - (a) for as long as it is needed for the purposes of recognition of the professional qualifications of the EPC applicant or the EPC holder; and
  - (b) as evidence of the recognition or transmission of the declaration required as part of the documents submitted under paragraph 12(2).
- (2) The Society is the controller within the meaning of article 2(d) of Directive 95/46/EC for the purposes of processing personal data in a person's European professional card or IMI file

## PART 3

European professional cards for establishment in the United Kingdom or another relevant European State

# European professional cards for establishment in a host State other than the United Kingdom

- 10.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Society for the purposes of establishment as a pharmacist in a relevant European State other than the United Kingdom; and

- (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the appropriate documents listed in paragraph 1 of Part A of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with and including the date on which the Society receives the EPC application, the Society must acknowledge receipt of the application and inform P of any missing document.
- (4) The Society must, within the period of one month beginning with and including the date of the relevant day—
  - (a) decide whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
  - (b) transmit its decision (under paragraph (a)) and the EPC application to the competent authority of P's host State (in order for that competent authority to decide whether to issue the European professional card: see article 4d(2) of the Directive) and, at the same time, inform P of the status of the application.
  - (5) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Society receives the EPC application, beginning with and including the day on which the Society receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Society.
  - (6) For the purpose of sub-paragraph (5), "relevant document" means—
    - (a) any previously missing document; or
    - (b) any document that is requested by the Society in connection with the EPC application before the day described in sub-paragraph (5)(a).

## Issue of European professional card for establishment in Northern Ireland

- 11.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to a competent authority of a relevant European State other than the United Kingdom for the purposes of establishment as a pharmacist in Northern Ireland;
  - (b) P's home State is not the United Kingdom;
  - (c) the competent authority of P's home State has decided whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
  - (d) the competent authority of P's home State transmits the decision described in paragraph (c) and the EPC application to the Society (in order for the Society to decide whether to issue the European professional card: see article 4d(2) of the Directive).
- (2) The Society may request additional information or a certified copy of a document from the competent authority of P's home State if it appears to the Society—
  - (a) that the applicant may not be entitled to hold a European professional card in accordance with this Schedule; or
  - (b) that a document or information supplied as part of the EPC application is not, or may not be, valid or correct.
- (3) Subject to sub-paragraphs (4) to (6), the Society must issue the European professional card within one month beginning with and including the date on which the Society received the EPC application from the competent authority of P's home State.
  - (4) The Society may extend the period in sub-paragraph (3)—

- (a) by two weeks; and
- (b) if it considers it necessary to do so, in particular for reasons relating to public health or the safety of recipients or prospective recipients of pharmacy services from the applicant, by a further two weeks following expiry of the two week extension under paragraph (a).
- (5) The Society must notify the applicant of any extension under sub-paragraph (4) and the reasons for it.
- (6) If the Society does not receive the documents or information necessary to determine whether to issue the European professional card, the Society may refuse to issue the card (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (7) If the Society fails to make a decision within the time limits set out in this paragraph—
  - (a) the applicant is to be treated as entitled to the European professional card; and
  - (b) the Society must issue the card to the applicant through the IMI immediately.

## PART 4

European professional cards for the provision of occasional pharmacy services in a relevant European State other than the United Kingdom

# Issue of European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom

- **12.**—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Society for the purposes of providing occasional pharmacy services (which do not fall within article 7(4) of the Directive) in one or more relevant European States other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the documents listed in paragraphs (a) to (c) of Part B of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with and including the date on which the Society receives the EPC application, the Society must acknowledge receipt of the application and inform P of any missing document.
- (4) The Society must within three weeks beginning with and including the date of the relevant day—
  - (a) consider P's EPC application, the authenticity and validity of the supporting documents and whether P is qualified as an automatically recognised pharmacist;
  - (b) decide whether to approve or refuse the application and whether to issue the European professional card; and
  - (c) transmit its decision (under paragraph (b)) and, if issued, the European professional card, to the competent authority of each host State concerned and, at the same time, inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (5) Unless its period of validity is extended under paragraph 13, a European professional card issued under this paragraph expires after 18 months beginning with and including the date on which it is issued.
  - (6) In this paragraph, "the relevant day" means the later of—

- (a) the day which falls one week after the day on which the Society receives the EPC application, beginning with and including the day on which the Society receives the EPC application; or
- (b) the day on which the last relevant document is received by the Society.
- (7) For the purpose of sub-paragraph (6), "relevant document" means—
  - (a) any previously missing document; or
  - (b) any document that is requested by the Society in connection with the EPC application before the day described in sub-paragraph (6)(a).

# Variation of a European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom

- **13.**—(1) This paragraph applies to an automatically recognised pharmacist ("P") who holds a European professional card issued under paragraph 12.
- (2) If P wishes to provide relevant pharmacy services after the end of the period of 18 months beginning with and including the date on which the card was issued, P may apply to the Society for the period of validity of the card to be extended by 18 months or such shorter period as may be specified in the application.
- (3) If P wishes to provide relevant pharmacy services in a host State not already specified on the card, P may apply to the Society for the list of host States specified on the card to be supplemented with the addition of such relevant European States as may be specified in the application.
- (4) An application under sub-paragraph (2) or (3) must be accompanied by details of any material changes to documentation or information that—
  - (a) was, pursuant to the Implementing Regulation 2015, provided to the Society with the EPC application under paragraph 12; and
  - (b) is recorded in P's IMI file.
  - (5) After considering an application under sub-paragraph (2) or (3), the Society must—
    - (a) accept the application (see sub-paragraph (6)); or
    - (b) if it appears to the Society that P is not, or may not be, entitled to hold a European professional card, reject the application and inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
  - (6) If the Society accepts the application, the Society must—
    - (a) issue an amended European professional card;
    - (b) transmit the card to the competent authority of each host State specified on the card; and
    - (c) notify P.
- (7) In this paragraph, "relevant pharmacy services" means occasional pharmacy services that are provided or to be provided in a relevant European State other than the United Kingdom.

## PART 5

European professional card: requirements and entitlements as to registration

## Requirement to register: establishment cases

**14.**—(1) A person ("P") who holds a valid European professional card for establishment in Northern Ireland is not entitled to practise as a pharmacist in Northern Ireland on the basis of establishment unless P complies with any requirements of, or under, this Order as to registration in Northern Ireland on that basis.

- (2) For the purposes of registration, P is not required—
  - (a) to resubmit any document or evidence which is contained in P's IMI file and which is still valid; or
  - (b) to submit further evidence, or a certificate from the competent authority in P's home State which certifies, that P holds a qualification listed in Annex V, point 5.6.2 of the Directive.

## Entitlement to registration: provision of occasional pharmacy services

- **15.**—(1) This paragraph applies to a person ("P") who holds a valid European professional card, in relation to the provision of occasional pharmacy services in the United Kingdom, which—
  - (a) has been transmitted to the Society through the IMI by the competent authority of P's home State (pursuant to article 4c of the Directive); or
  - (b) has been issued by the Society under regulation 52 of the General Systems Regulations.
  - (2) Subject to sub-paragraphs (3) to (6)—
    - (a) P is entitled to be registered in the register mentioned in Article 6(1)(d) and the Society must give effect to that entitlement; and
    - (b) if P is not registered in the register mentioned in Article 6(1)(d), P is treated as being so registered.
- (3) If P's European professional card has been issued by the Society under regulation 52 of the General Systems Regulations, P's entitlement to be registered in the register mentioned in Article 6(1)(d) ceases at the end of the period of 12 months beginning with and including the date on which the Society issued P's card.
  - (4) This sub-paragraph applies if—
    - (a) P's European professional card is, or becomes, invalid;
    - (b) P is subject to a disqualifying decision; or
    - (c) P becomes established as a pharmacist in the United Kingdom.
  - (5) If sub-paragraph (4) applies—
    - (a) the Society may refuse to register P in, or may remove P from, the register mentioned in Article 6(1)(d); and
    - (b) sub-paragraph (2) ceases to apply.
- (6) This paragraph is without prejudice to any other provision of this Order under which a person's registration under Article 6 may be suspended or under which a person may be removed from a register kept under Article 6.

## PART 6

## Conditions in relation to fitness to practise

## Conditions in relation to fitness to practise: providers of occasional pharmacy services

- 16.—(1) Sub-paragraph (2) applies in relation to a person ("P") who—
  - (a) falls within paragraph 15(1); and
  - (b) is registered in the register mentioned in Article 6(1)(d).
- (2) If it falls to be decided whether P's fitness to practise is or may be impaired on the ground of misconduct for any of the purposes of this Order, then "misconduct" includes any act or omission by P during the course of P's provision of occasional pharmacy services—

- (a) which constitutes a breach of a condition or limitation to which P is subject in relation to P's practice as a pharmacist in P's home State; or
- (b) which would constitute a breach of the condition or limitation mentioned in paragraph (a) if that condition or limitation applied in relation to P's practice as a pharmacist outside of P's home State.

## **SCHEDULE 2D**

Article 22A

## The Directive: Functions of the Society under Article 22A

Provision of Directive	Function of Society
Article 4a	Ensuring that the holder of a European professional card benefits from all of the rights conferred by articles 4b to 4e of the Directive.
	Charging reasonable fees to cover the costs of processing applications for or in relation to European professional cards under Schedule 2C and under Part 4 of the General Systems Regulations.
Article 4b	Enabling pharmacists to apply for a European professional card in accordance with Schedule 2C and in accordance with Part 4 of the General Systems Regulations.
Article 4c	Verifying the application and supporting documents in the IMI file and issuing the European professional card for pharmacists for the temporary and occasional provision of pharmacy services other than those covered by article 7(4) of the Directive.
Article 4d	Verifying the authenticity and validity of the application and supporting documents in the IMI file for the purpose of issuing the European professional card for pharmacists for establishment or for the temporary and occasional provision of pharmacy services under article 7(4) of the Directive.
Article 4e	Updating, in a timely manner, the IMI file of a holder of a European professional card with information about disciplinary actions or criminal sanctions regarding a prohibition or restriction and which have consequences for the pursuit of any professional activities by that person under the Directive.
Article 4f	Considering applications for partial access to the profession of pharmacist under regulations 10 and 11 of the General Systems Regulations.
Article 7(2)(b)	Issuing certificates containing attestations in relation to persons established as a pharmacist in Northern Ireland.
Article 7(2a)	Requesting information from, and providing information to, other competent authorities in accordance with the declaration provided by the applicant to provide pharmacy services on a temporary and occasional basis.
Article 8(1)	In the event of justified doubts, receiving information from, or providing information to, other competent authorities in relation to—  (a) the legality of a person's establishment as a pharmacist in Northern Ireland;
	<ul><li>(b) the good conduct of such a person;</li><li>(c) the absence of any disciplinary or criminal sanctions of a</li></ul>
	professional nature against such a person.
	Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.
Article 8(2)	Receiving information from, or providing information to, other

competent authorities in connection with the investigation of complaints made against persons providing services as a pharmacist. Issuing certificates of effective and lawful practice in Northern Ireland Article 23(1) to pharmacists. Issuing certificates stating that NI pharmacy qualifications, which do Article 23(6) not correspond to the titles set out in respect of the United Kingdom at point 5.6.2 of Annex V to the Directive, certify successful completion of training in pharmacy— (a) that is in accordance with article 44 of the Directive; or (b) that under article 22(a) of the Directive (part-time training), is to be treated as in accordance with article 44 of the Directive. Providing information to other competent authorities concerning the Article 50(1) and training in Northern Ireland of a pharmacist to whom Chapter 1 of Part paragraph 1(b) of 3 of the General Systems Regulations applies. Annex VII Issuing, in respect of practice as a pharmacist, the certificates of current Article 50(1) and paragraph 1(d) of professional status referred to in sub-paragraph (d) of paragraph 1 of Annex VII to the Directive within the time limits set by that sub-Annex VII paragraph. Article 50(1) and Issuing certificates stating that evidence of NI pharmacy qualifications is that covered by the Directive. paragraph 2 of Annex VII Article 50(2) In cases of justified doubts— (a) requiring confirmation of the authenticity of non-UK pharmacy qualifications; (b) requiring confirmation that holders of non-UK pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or are to be treated as satisfying those conditions under article 22(a) of the Directive; (c) providing confirmation to competent authorities of other relevant European States of the authenticity of any person's NI pharmacy qualification; (d) providing confirmation that holders of NI pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive or are to be treated as satisfying those conditions under article 22(a) of the Directive. Article 50(3) In cases of justified doubts— (a) verifying information provided in connection with non-UK pharmacy qualifications awarded following training in a relevant European State other than the State in which the qualification was awarded; (b) providing information in connection with a person's NI pharmacy qualification awarded following training in another relevant European State. In the event of justified doubts, seeking confirmation from, or Article 50(3a) providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the profession of pharmacist as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's professional activities. Article 50(3b) Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI. Ensuring that any language controls imposed on a pharmacist are Article 53 compliant with article 53 of the Directive. When considering an application for registration as a pharmacist. Article 55a

ensuring that in respect of professional traineeships—

(a) traineeships undertaken in a relevant European State are recognised in accordance with published guidelines; and

(b) traineeships undertaken in a third country are taken into account.

Ensuring the confidentiality of information exchanged with other Article 56(1) competent authorities.

Article 56(2) Receiving information from, or providing information to, other competent authorities regarding disciplinary action, criminal sanctions or other serious circumstances likely to have consequences for practise as a pharmacist.

Where such information is received by the Society—

- (a) examining the veracity of the circumstances;
- (b) deciding the nature and scope of any investigations that need to be carried out;
- (c) informing other competent authorities of the Society's conclusions. Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI.

Ensuring that the exchange of information carried out in accordance Article 56(2a) with article 56(2) of the Directive takes place through the IMI.

> Informing all other competent authorities, by way of an alert through the IMI, about a pharmacist whose professional activities have been restricted or prohibited, even temporarily, within three days beginning with and including the date of adoption of the decision; ensuring the information provided is limited to the information referred to in article 56a(2) of the Directive.

Informing all other competent authorities, by way of an alert through Article 56a(3) the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications, within three days beginning with and including the date of the finding.

Ensuring that the processing of personal data for the purposes of the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC.

Informing all other competent authorities through the IMI without delay when-

- (a) a prohibition or a restriction referred to in article 56a(1) of the Directive has expired;
- (b) there is a change to the prohibition or restriction period notified under article 56a(2) of the Directive.

Notifying the pharmacist, in respect of whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the pharmacist—

- (a) is the subject of an alert sent under article 56a(1) or (3) of the Directive:
- (b) has the right to appeal the decision or to apply for rectification of the decision:
- (c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.

Informing competent authorities, where applicable, that an alert is subject to appeal proceedings by the pharmacist.

Article 56a(7) Ensuring that an alert made under article 56a(1) of the Directive is deleted from the IMI within three days of, beginning with and including—

Article 56a (1) and (2)

Article 56a(4)

Article 56a(5)

Article 56a(6)

- (a) the date of adoption of the revoking decision; or
- (b) the date of expiry of the prohibition or restriction referred to in that article.

Article 57a(1)

Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications as a pharmacist may be easily completed by the applicant remotely and by electronic means."

#### **CHAPTER 2**

# AMENDMENT OF THE REGISTRATION OF PHARMACEUTICAL CHEMISTS (EXEMPT PERSONS) REGULATIONS (NORTHERN IRELAND) 2008

### Introductory

**26.** The Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008(a) are amended in accordance with this Chapter.

## Amendment of regulation 2

- **27.**—(1) Regulation 2 (manner and content of applications by exempt persons for registration in the register of pharmaceutical chemists) is amended as follows.
  - (2) In paragraph (1), for "(6)" substitute "(6A)".
  - (3) After paragraph (6), insert—
    - "(6A) In the event of justified doubts, the registrar shall accept a certificate issued by a competent authority in E's attesting State which confirms that E is not suspended or prohibited from practising as a pharmacist as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of E's professional activities.".
  - (4) In paragraph (7), for "(6)" substitute "(6A)".
  - (5) In paragraph (8), for ", (4), (5) or (6)" substitute "to (6A)".

## **Insertion of regulation 3**

28. After regulation 2, insert—

#### "Review

- **3.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to these Regulations by the European Oualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

#### **CHAPTER 3**

### AMENDMENT OF THE PHARMACY ORDER 2010

## Introductory

**29.** The Pharmacy Order 2010(**b**) is amended in accordance with this Chapter.

<sup>(</sup>a) S.R. (N.I.) 2008 No. 193.

<sup>(</sup>**b**) S.I. 2010/231.

#### Amendment of article 3

- **30.**—(1) Article 3(1) (interpretation)(**a**) is amended as follows.
- (2) For the definition of "General Systems Regulations", substitute—
  - ""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015;".
- (3) In the appropriate places, insert—
  - ""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";
  - ""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12th July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";
  - ""European professional card" has the meaning given in the Directive;";
  - ""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;";
  - ""IMI file" means a secure personal account in the IMI that is created in relation to an applicant for a European professional card by means of an online tool provided by the European Commission;";
  - ""professional traineeship" means a period of professional practice, carried out under supervision, that—
  - (a) constitutes a condition for access to the profession of pharmacist or pharmacy technician in the country in which it is carried out; and
  - (b) takes place during or after completion of a course of education leading to an educational qualification pursued for the purpose of entry to that profession;";
  - ""third country" means a country other than a relevant European State.".

## **Amendment of article 21**

- **31.**—(1) Article 21 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacists) is amended as follows.
  - (2) In paragraph (1)(c)(i), for "3(9)(a) or (e)" substitute "3(8)(a) or (e)".
  - (3) In paragraph (1)(c)(ii)—
    - (a) for "20 to 26" substitute "27 to 34";
    - (b) for "3(4)" substitute "3(5)".

## Amendment of article 23

- **32.**—(1) Article 23 (form, manner and content of applications for entry or for renewal of an entry in the register: pharmacists and pharmacy technicians) is amended as follows.
  - (2) In paragraph (1)(c)(iv)(bb), omit the "and" at the end.
  - (3) After paragraph (1)(c)(v), insert—
    - "(vi) if the applicant is an exempt person, in the event of justified doubts, confirmation from the competent authority of a relevant European State that the applicant is not suspended or prohibited from practising as a pharmacist or pharmacy technician as a result of serious professional misconduct or

<sup>(</sup>a) Regulation 3 was amended by S.I. 2015/806. There are other amendments which are not relevant to these Regulations.

conviction of criminal offences relating to the pursuit of any of the applicant's professional activities; and".

#### **Insertion of article 33A**

**33.** After article 33 (visiting pharmacists and pharmacy technicians from relevant European States), insert—

#### "European professional card

- **33A.**—(1) Schedule 2A (Directive 2005/36/EC: European professional card) has effect.
- (2) The Council may charge a reasonable fee to cover the costs of processing an application for or in relation to a European professional card under Schedule 2A.".

#### **Amendment of article 39**

- **34.**—(1) Article 39 (appealable decisions)(a) is amended as follows.
- (2) In paragraph (1)(r), omit the "and" at the end.
- (3) After paragraph (1)(s), insert—
  - "(t) a decision of the Council under regulation 67 of the General Systems Regulations to send an alert about a person; and
  - (u) a decision of the Council, under Schedule 2A, or under Part 4 of the General Systems Regulations, to revoke, or not to issue, extend or vary, a European professional card."
- (4) After paragraph (1), insert—

"(1A) A failure by the Council to make a decision in relation to a European professional card within the time limit under paragraph 10(4) or 12(4) of Schedule 2C or regulation 51(1) or 56(1) of the General Systems Regulations is also appealable for the purposes of article 40.".

#### Amendment of article 40

- **35.**—(1) Article 40 (appeals to the Appeals Committee)(**b**) is amended as follows.
- (2) After paragraph (1), insert—
  - "(1A) A person in respect of whom the Council has failed to make a decision in relation to a European professional card within the applicable time as described by article 39(1A) may appeal to the Appeals Committee by giving notice of appeal to the Registrar within 28 days beginning with the date by which the Council was required to have notified the person of the decision."
- (3) In paragraph (7)(b), after "against" insert "or, in the case of an appeal against a decision falling within article 39(1)(t), direct that the alert be withdrawn or amended".
  - (4) In paragraph (7)(c), omit the "or" at the end.
  - (5) After paragraph (7)(c), insert—
    - "(ca) with respect to an appeal under paragraph (1A), enter any decision which could have been taken by the Council; or".

<sup>(</sup>a) Article 39 was amended by S.I. 2014/1887 and 2015/806.

<sup>(</sup>**b**) Article 40 was amended by S.I. 2015/806.

#### Amendment of article 41

- **36.**—(1) Article 41 (powers of relevant court on appeal from Appeals Committee) is amended as follows.
- (2) In paragraph (4)(b), after "against" insert "or, in the case of an appeal against a decision to send an alert about a person, direct that the alert be withdrawn or amended".
  - (3) In paragraph (4)(c), omit the "or" at the end.
  - (4) After paragraph (4)(c), insert—
    - "(ca) with respect to an appeal under article 40(1A), enter any decision which could have been taken by the Council; or".

#### Amendment of article 42

- 37.—(1) Article 42 (education, training and acquisition of experience) is amended as follows.
- (2) In paragraph (1)(a), omit "or (c) or article 22(1)(b)".

#### **Insertion of article 42A**

**38.** After article 42, insert—

#### "Professional traineeships carried out in other relevant European States, etc.

- **42A.**—(1) If a person is required to carry out a professional traineeship of a particular standard in order to be appropriately qualified under article 21 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacists) or article 22 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacy technicians), a professional traineeship of an equivalent standard which has been carried out by a person whose home Member State is the United Kingdom and which satisfies the conditions in paragraph (2) is treated as meeting that requirement.
  - (2) The conditions are that
    - (a) at least three quarters of the time of which the professional traineeship consisted, or such lesser proportion as the Council may consider appropriate in any particular case, was spent in the United Kingdom; and
    - (b) the remaining time of which the professional traineeship consisted was spent in another relevant European State.
  - (3) Paragraph (4) applies if—
    - (a) a person whose home Member State is the United Kingdom applies to the Council to be entered in the Register as a pharmacist or as a pharmacy technician; and
    - (b) the person has carried out a professional traineeship, all or part of which was carried out in a third country.
- (4) The Registrar must take the professional traineeship into account when considering whether the person satisfies any requirement under article 21 or 22 for entry on the Register which includes a requirement to carry out a professional traineeship in the United Kingdom.
- (5) The Council must publish guidelines on the organisation and recognition of professional traineeships carried out in relevant European States and third countries (including, in particular, guidelines on the role of the supervisor of the professional traineeship).
- (6) In this article, "home Member State" has the meaning given in article 1 of the Directive.".

#### Amendment of article 67

- **39.** In article 67 (the Directive: designation of competent authority etc), for paragraphs (4) to (6) substitute—
  - "(4) The Secretary of State may give directions to the Council as to matters of administration in connection with the functions of the Council specified in Schedule 3.
    - (5) The Council must comply with a direction given under paragraph (4).
    - (6) In Schedule 3—
      - (a) "GB pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by the Council;
      - (b) "non-UK pharmacy qualification" means evidence of formal qualifications in pharmacy, listed in Annex V, point 5.6.2 of the Directive, awarded to a person by a competent authority of a relevant European State other than the United Kingdom.".

#### **Insertion of article 71**

**40.** After article 70 (Privy Council procedures etc), insert—

## "Review

- **71.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to this Order by the European Qualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

## Amendment of Schedule 2

- **41.**—(1) Schedule 2 (visiting practitioners from relevant European States) is amended as follows.
  - (2) For paragraph 1(1), substitute—
    - "(1) This Part of this Schedule applies to a person who—
      - (a) is an exempt person who is lawfully established as a pharmacist in a relevant European State other than the United Kingdom; and
      - (b) is not a person to whom paragraph 15 of Schedule 2A (European professional card and entitlement to registration: provision of occasional pharmacy services) to this Order or paragraph 15 of Schedule 2C (European professional card and entitlement to registration: provision of occasional pharmacy services) to the Pharmacy (Northern Ireland) Order 1976 applies."
  - (3) In paragraph 3(b)—
    - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e)";
    - (b) for "14 to 16" substitute "19 to 23".
  - (4) In paragraph 4—
    - (a) in sub-paragraph (2)(a)—
      - (i) in sub-paragraph (i), omit the "and" at the end;
      - (ii) after sub-paragraph (ii), insert—
        - "(iii) confirms that the practitioner does not have a criminal conviction; and

- (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a pharmacist;";
- (b) after sub-paragraph (2)(a), insert—
  - "(aa) a written declaration as to whether the practitioner has the necessary knowledge of English;";
- (c) in sub-paragraph (3), after "(2)(a)" insert "or (aa)".
- (5) After paragraph 4, insert—

## "First provision of services: visiting practitioners from Northern Ireland

- **4A.**—(1) The Registrar must treat a visiting practitioner who—
  - (a) applies to be entered in Part 4 of the Register as a visiting practitioner; and
  - (b) is registered in the register kept under Article 6(1)(d) of the Pharmacy (Northern Ireland) Order 1976 relating to pharmacists who are visiting practitioners to Northern Ireland,

as complying with the requirements of paragraph 4.

- (2) The Registrar may require the visiting practitioner to provide additional information concerning his or her professional qualifications as a result of differences in the way that the profession is regulated in different parts of the United Kingdom.
- (3) Sub-paragraph (1) does not apply if the Registrar has required the visiting practitioner to provide information under sub-paragraph (2) and the visiting practitioner has not done so.".
- (6) In paragraph 5(2)—
  - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e);
  - (b) for "14 to 16" substitute "19 to 23".
- (7) In paragraph 7(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a pharmacist".
  - (8) In paragraph 11, for "8" substitute "12".
  - (9) In paragraph 12—
    - (a) in sub-paragraph (2)(a)—
      - (i) in sub-paragraph (i), omit the "and" at the end;
      - (ii) after sub-paragraph (ii), insert—
        - "(iii) confirms that the practitioner does not have a criminal conviction; and
        - (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a pharmacy technician;";
    - (b) after sub-paragraph (2)(a), insert—
      - "(aa) a written declaration as to whether the practitioner has the necessary knowledge of English;";
    - (c) in sub-paragraph (3), after "(2)(a)" insert "or (aa)".
- (10) In paragraph 15(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a pharmacy technician".

#### Insertion of Schedule 2A

42. After Schedule 2, insert—

## Directive 2005/36/EC: European professional card

## PART 1

#### General

#### Introductory

**1.** This Schedule supplements the rights and obligations set out in the Implementing Regulation 2015.

## Interpretation

#### 2. In this Schedule—

"automatically recognised pharmacist" means a person who is entitled to have his or her qualifications as a pharmacist automatically recognised under articles 21, 23, 49a or 49b of the Directive:

"disqualifying decision" means a decision made by a competent authority or a judicial authority in a person's home State or host State that has the effect that—

- (a) the person ceases to be registered or otherwise officially recognised as a pharmacist in that State; or
- (b) the person is prohibited, permanently or temporarily, from practising as a pharmacist in that State;

"EPC applicant" means a person making, or who has made, an EPC application;

"EPC application" means an application for a European professional card made by a person who is seeking to practise as an automatically recognised pharmacist;

"EPC holder" means a person who holds a valid European professional card as a result of an EPC application;

"home State" means the relevant European State specified by an EPC applicant in his or her EPC application in accordance with article 4 of the Implementing Regulation 2015;

"host State" means the relevant European State in which an EPC applicant seeks to practise as a pharmacist;

"Implementing Regulation 2015" means Commission Implementing Regulation (EU) No 983 of 2015 on the procedure for issuance of the European professional card and the application of the alert mechanism pursuant to the Directive;

"missing document" means a document which an EPC applicant was required to provide with the EPC application but which the EPC applicant has not provided;

"occasional pharmacy services" means the provision of services as a pharmacist on a temporary and occasional basis.

## PART 2

General functions of the Council in relation to European professional cards

## Council not to request resubmission of valid documents

**3.** If a person ("P") who has already made an application for or in relation to a European professional card makes a subsequent or further application for or in relation to a European professional card, the Council may not request resubmission of documents that are

contained in P's IMI file and which are still valid for the purposes of processing P's subsequent or further application.

## Power to revoke a European professional card

- **4.**—(1) The Council may revoke a European professional card issued under this Schedule if it appears to the Council that the person ("P") to whom the card was issued is not entitled to hold the card.
- (2) P is not entitled to hold a European professional card if, in particular, P is subject to a disqualifying decision.

#### Rectification of the European professional card or the IMI file

- **5.**—(1) If an automatically recognised pharmacist ("P") holds a European professional card issued by the Council, P may, at any time, make a written request to the Council to rectify inaccurate or incomplete data in P's IMI file or to delete or block P's IMI file if it contains inaccurate or incomplete data.
- (2) If the Council is satisfied that the data in P's IMI file is inaccurate or incomplete, the Council must comply with a request by P under sub-paragraph (1).
  - (3) The Council must notify P of P's right under sub-paragraph (1)—
    - (a) at the time P's European professional card is issued;
    - (b) within the period ending two years after the date on which the European professional card was issued; and
    - (c) subsequently at intervals not exceeding two years from the date of the previous notification.
- (4) A notification under sub-paragraph (3)(b) or (c) must be sent to P by means of an automatic reminder sent through the IMI.
- (5) The Council must not charge P a fee in relation to the making of a written request under sub-paragraph (1) or in relation to complying with, or responding to, such a request.
  - (6) If—
    - (a) P's European professional card was issued for the purposes of establishment;
    - (b) P asks the Council to delete P's IMI file; and
    - (c) P's host State is the United Kingdom,

the Council must provide P with evidence confirming that the Council recognises P's professional qualifications.

## Duty to give reasons and to notify of right of appeal

**6.** If the Council refuses to issue, extend or vary, or decides to revoke, a European professional card under this Schedule, the Council must notify the EPC applicant or the EPC holder of the reasons for that decision and of his or her right of appeal under article 40.

## Updating the IMI file: disciplinary action or criminal sanctions

- 7.—(1) This paragraph applies if a person ("P")—
  - (a) makes an EPC application to the Council; or
  - (b) is an EPC holder and P's European professional card was issued by the Council.
- (2) The Council must update P's IMI file in accordance with sub-paragraphs (3) and (4) in a timely manner.
- (3) The Council must add to P's IMI file information, regarding disciplinary action or criminal sanctions, which—

- (a) relates to a prohibition or restriction on P's entitlement to practise as a pharmacist; or
- (b) has consequences for the pursuit of any activities by P, in P's capacity as a pharmacist.
- (4) The Council must delete from P's IMI file information regarding disciplinary action or criminal sanctions that is no longer required.
- (5) The Council must immediately inform P and the competent authorities of other relevant European States that have access to P's IMI file of any update under this paragraph.
- (6) The information that may be added or deleted under this paragraph is limited to details of—
  - (a) P's identity;
  - (b) information about the national authority or court which has made a decision on a restriction or prohibition applying to P;
  - (c) the scope of the restriction or prohibition; and
  - (d) the period for which the restriction or prohibition applies.

#### Access to data

- **8.**—(1) The Council may access information on the IMI file of an EPC applicant or an EPC holder, in accordance with Directive 95/46/EC, only if the United Kingdom is the home State or the host State of the applicant or the holder.
- (2) The Council must provide an EPC applicant or an EPC holder with information on the content of his or her IMI file on request.

#### **Processing data**

- **9.**—(1) The Council may process personal data to which it has access under paragraph 8—
  - (a) for as long as it is needed for the purposes of recognition of the professional qualifications of the EPC applicant or the EPC holder; and
  - (b) as evidence of the recognition or transmission of the declaration required as part of the documents submitted under paragraph 12(2).
- (2) The Council is the controller within the meaning of article 2(d) of Directive 95/46/EC for the purposes of processing personal data in a person's European professional card or IMI file.

#### PART 3

European professional cards for establishment in the United Kingdom or another relevant European State

# European professional cards for establishment in a host State other than the United Kingdom

- 10.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Council for the purposes of establishment as a pharmacist in a relevant European State other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.

- (2) P must submit with the EPC application the appropriate documents listed in paragraph 1 of Part A of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with the date on which it receives the EPC application, the Council must acknowledge receipt of the application and inform P of any missing document.
  - (4) The Council must, within the period of one month beginning with the relevant day—
    - (a) decide whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
    - (b) transmit its decision (under paragraph (a)) and the EPC application to the competent authority of P's host State (in order for that competent authority to decide whether to issue the European professional card: see article 4d(2) of the Directive) and, at the same time, inform P of the status of the application.
  - (5) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Council receives the application; or
    - (b) the day on which the last relevant document is received by the Council.
  - (6) For the purpose of sub-paragraph (5), "relevant document" means—
    - (a) any previously missing document; or
    - (b) any document that is requested by the Council in connection with the EPC application before the day described in sub-paragraph (5)(a).

#### Issue of European professional card for establishment in Great Britain

- 11.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to a competent authority of a relevant European State other than the United Kingdom for the purposes of establishment as a pharmacist in Great Britain;
  - (b) P's home State is not the United Kingdom;
  - (c) the competent authority of P's home State has decided whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised pharmacist; and
  - (d) the competent authority of P's home State transmits the decision described in paragraph (c) and the EPC application to the Council (in order for the Council to decide whether to issue the European professional card: see article 4d(2) of the Directive).
- (2) The Council may request additional information or a certified copy of a document from the competent authority of P's home State if it appears to the Council—
  - (a) that the applicant may not be entitled to hold a European professional card in accordance with this Schedule; or
  - (b) that a document or information supplied as part of the EPC application is not, or may not be, valid or correct.
- (3) Subject to sub-paragraphs (4) to (6), the Council must issue the European professional card within one month of receipt of the EPC application from the competent authority of P's home State.
  - (4) The Council may extend the period in sub-paragraph (3)—
    - (a) by two weeks; and

- (b) if it considers it necessary to do so, in particular for reasons relating to public health or the safety of recipients or prospective recipients of pharmacy services from the applicant, by a further two weeks following expiry of the two week extension under paragraph (a).
- (5) The Council must notify the applicant of any extension under sub-paragraph (4) and the reasons for it.
- (6) If the Council does not receive the documents or information necessary to determine whether to issue the European professional card, the Council may refuse to issue the card (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (7) If the Council fails to make a decision within the time limits set out in this paragraph—
  - (a) the applicant is to be treated as entitled to the European professional card; and
  - (b) the Council must issue the card to the applicant through the IMI immediately.

#### PART 4

European professional cards for the provision of occasional pharmacy services in a relevant European State other than the United Kingdom

## Issue of European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom

- 12.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Council for the purposes of providing occasional pharmacy services (which do not fall within article 7(4) of the Directive) in one or more relevant European States other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the documents listed in paragraphs (a) to (c) of Part B of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with the date on which the Council receives the EPC application, the Council must acknowledge receipt of the application and inform P of any missing document.
  - (4) The Council must within three weeks of the relevant dav—
    - (a) consider P's EPC application, the authenticity and validity of the supporting documents and whether P is qualified as an automatically recognised pharmacist;
    - (b) decide whether to approve or refuse the application and whether to issue the European professional card; and
    - (c) transmit its decision (under paragraph (b)) and, if issued, the European professional card, to the competent authority of each host State concerned and, at the same time, inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (5) Unless its period of validity is extended under paragraph 13, a European professional card issued under this paragraph expires 18 months after the date on which it is issued.
  - (6) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Council receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Council.

- (7) For the purpose of sub-paragraph (6), "relevant document" means—
  - (a) any previously missing document; or
  - (b) any document that is requested by the Council in connection with the EPC application before the day described in sub-paragraph (6)(a).

## Variation of a European professional card for the provision of occasional pharmacy services in a host State other than the United Kingdom

- **13.**—(1) This paragraph applies to an automatically recognised pharmacist ("P") who holds a European professional card issued under paragraph 12.
- (2) If P wishes to provide relevant pharmacy services after the end of the period of 18 months beginning with the date on which the card was issued, P may apply to the Council for the period of validity of the card to be extended by 18 months or such shorter period as may be specified in the application.
- (3) If P wishes to provide relevant pharmacy services in a host State not already specified on the card, P may apply to the Council for the list of host States specified on the card to be supplemented with the addition of such relevant European States as may be specified in the application.
- (4) An application under sub-paragraph (2) or (3) must be accompanied by details of any material changes to documentation or information that—
  - (a) was, pursuant to the Implementing Regulation 2015, provided to the Council with the EPC application under paragraph 12; and
  - (b) is recorded in P's IMI file.
  - (5) After considering an application under sub-paragraph (2) or (3), the Council must—
    - (a) accept the application (see sub-paragraph (6)); or
    - (b) if it appears to the Council that P is not, or may not be, entitled to hold a European professional card, reject the application and inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
  - (6) If the Council accepts the application, the Council must—
    - (a) issue an amended European professional card;
    - (b) transmit the card to the competent authority of each host State specified on the card; and
    - (c) notify P.
- (7) In this paragraph, "relevant pharmacy services" means occasional pharmacy services that are provided or to be provided in a relevant European State other than the United Kingdom.

## PART 5

European professional card: requirements and entitlements as to registration

#### Requirement to register: establishment cases

- **14.**—(1) A person ("P") who holds a valid European professional card for establishment in Great Britain is not entitled to practise as a pharmacist in Great Britain on the basis of establishment unless P complies with any requirements of, or under, this Order as to registration in Great Britain on that basis.
- (2) For the purposes of registration, P is not required to resubmit any document or evidence which is contained in P's IMI file and which is still valid.

## Entitlement to registration: provision of occasional pharmacy services

- **15.**—(1) This paragraph applies to a person ("P") who holds a valid European professional card, in relation to the provision of occasional pharmacy services in the United Kingdom, which—
  - (a) has been transmitted to the Council through the IMI by the competent authority of P's home State (pursuant to article 4c of the Directive); or
  - (b) has been issued by the Council under regulation 52 of the General Systems Regulations.
  - (2) Subject to sub-paragraphs (3) to (6)—
    - (a) P is entitled to be entered in Part 4 of the Register and the Council must give effect to that entitlement; and
    - (b) if P is not entered in Part 4 of the Register, P is treated as being so entered.
- (3) If P's European professional card has been issued by the Council under regulation 52 of the General Systems Regulations, P's entitlement to be entered in Part 4 of the Register ceases at the end of the period of 12 months beginning with the date on which the Council issued P's card.
  - (4) This sub-paragraph applies if—
    - (a) P's European professional card is, or becomes, invalid;
    - (b) P is subject to a disqualifying decision; or
    - (c) P becomes established as a pharmacist in the United Kingdom.
  - (5) If sub-paragraph (4) applies—
    - (a) the Council may refuse to enter P in, or may remove P from, Part 4 of the Register; and
    - (b) sub-paragraph (2) ceases to apply.
- (6) This paragraph is without prejudice to any other provision of this Order under which the name of a registered pharmacist may be removed from the register or under which the registration of a registered pharmacist may be suspended.

## PART 6

## Conditions in relation to fitness to practise

## Conditions in relation to fitness to practise: providers of occasional pharmacy services

- 16.—(1) Sub-paragraph (2) applies in relation to a person ("P") who—
  - (a) falls within paragraph 15(1); and
  - (b) is entered in Part 4 of the Register.
- (2) If it falls to be decided whether P's fitness to practise is or may be impaired on the ground of misconduct for any of the purposes of this Order, then "misconduct" includes any act or omission by P during the course of P's provision of occasional pharmacy services—
  - (a) which constitutes a breach of a condition or limitation to which P is subject in relation to P's practice as a pharmacist in P's home State; or
  - (b) which would constitute a breach of the condition or limitation mentioned in paragraph (a) if that condition or limitation applied in relation to P's practice as a pharmacist outside of P's home State.".

#### Amendment of Schedule 3

**43.**—(1) Schedule 3 (the Directive: Designation of Competent Authority etc)(a) is amended as follows.

(2) Before the entry relating to article 7(2)(b), insert—

"Article 4a Ensuring that the holder of a European professional card benefits

from all of the rights conferred by articles 4b to 4e of the

Directive.

Charging reasonable fees to cover the costs of processing applications for or in relation to European professional cards under Schedule 2A and under Part 4 of the General Systems

Regulations.

Article 4b Enabling pharmacists to apply for a European professional card

in accordance with Schedule 2A and in accordance with Part 4 of

the General Systems Regulations.

Verifying the application and supporting documents in the IMI Article 4c

> file and issuing the European professional card for pharmacists for the temporary and occasional provision of pharmacy services

other than those covered by article 7(4) of the Directive.

Article 4d Verifying the authenticity and validity of the application and

> supporting documents in the IMI file for the purpose of issuing the European professional card for pharmacists for establishment or for the temporary and occasional provision of pharmacy

services under article 7(4) of the Directive.

Article 4e Updating, in a timely manner, the IMI file of a holder of a

> European professional card with information about disciplinary actions or criminal sanctions regarding a prohibition or restriction and which have consequences for the pursuit of any

professional activities by that person under the Directive.

Article 4f Considering applications for partial access to the professions of

pharmacist and pharmacy technician under regulations 10 and 11

of the General Systems Regulations."

(3) After the entry relating to article 7(2)(b), insert—

"Article 7(2a) Requesting information from, and providing information to.

other competent authorities in accordance with the declaration provided by the applicant to provide pharmacy services on a

temporary and occasional basis."

(4) In the entry relating to article 8(1)—

- (a) for "Receiving", substitute "In the event of justified doubts, receiving";
- (b) after paragraph (c), insert—

"Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.".

(5) After the entry relating to article 50(3) insert—

"Article 50(3a) In the event of justified doubts, seeking confirmation from, or

providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the profession of pharmacist or pharmacy technician as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's

professional activities.

<sup>(</sup>a) Schedule 3 was amended by S.I. 2015/806.

Article 50(3b)

Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI."

(6) After the entry relating to article 53, insert—

"Article 55a

When considering an application for registration as a pharmacist or as a pharmacy technician, ensuring that in respect of professional traineeships—

(a) traineeships undertaken in a relevant European State are recognised in accordance with published guidelines;(b) traineeships undertaken in a third country are taken into

account."

(7) In the entry relating to article 56(2), after paragraph (c), insert—

"Ensuring that the processing of personal data for the purposes of the exchange of information in accordance article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI."

(8) After the entry relating to article 56(2), insert—

"Article 56(2a) Ensuring that the exchange of information carried out in

accordance with article 56(2) of the Directive takes place

through the IMI.

Article 56a(1) and (2) Informing all other competent authorities, by way of an alert

through the IMI, about a pharmacist or a pharmacy technician whose professional activities have been restricted or prohibited, even temporarily, within three days from the date of adoption of the decision; ensuring the information provided is limited to the information referred to in article 56c(2) of the Directive

information referred to in article 56a(2) of the Directive.

Article 56a(3) Informing all other competent authorities, by way of an alert

through the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications,

within three days from the date of the finding.

Article 56a(4) Ensuring that the processing of personal data for the purposes of

the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with Directive 95/46/EC

and Directive 2002/58/EC.

Article 56a(5) Informing all other competent authorities through the IMI

without delay when-

(a) a prohibition or a restriction referred to in article 56a(1) of the

Directive has expired;

(b) there is a change to the prohibition or restriction period

notified under article 56a(2) of the Directive.

Article 56a(6) Notifying the pharmacist or pharmacy technician, in respect of

whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the pharmacist

or pharmacy technician—

(a) is the subject of an alert sent under article 56a(1) or (3) of the

Directive;

(b) has the right to appeal the decision or to apply for

rectification of the decision;

(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.

Informing competent authorities, where applicable, that an alert is subject to appeal proceedings by the pharmacist or pharmacy

technician.

Article 56a(7) Ensuring that an alert made under article 56a(1) of the Directive

is deleted from the IMI within three days of—

- (a) the date of adoption of the revoking decision; or
- (b) the expiry of the prohibition or restriction referred to in that article.

Article 57a(1)

Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications as a pharmacist or a pharmacy technician may be easily completed by the applicant remotely and by electronic means."

#### **CHAPTER 4**

## AMENDMENT OF THE GENERAL PHARMACEUTICAL COUNCIL (REGISTRATION RULES) ORDER OF COUNCIL 2010

## Introductory

**44.** The General Pharmaceutical Council (Registration) Rules 2010, which are set out in the Schedule to the General Pharmaceutical Council (Registration Rules) Order of Council 2010(a), are amended in accordance with this Chapter.

#### Amendment of rule 10

- **45.**—(1) Rule 10 (entry in the register) is amended as follows.
- (2) In paragraph (3)(h), before "E must also provide", insert ", subject to paragraph (3ZA)".
- (3) In paragraph (3)(i)(ii) for "23 and 24" substitute "30 and 31".
- (4) After paragraph (3), insert—

"(3ZA) The requirement to provide a certificate under paragraph (3)(h) does not apply if the applicant holds a valid European professional card (as a pharmacist).".

## PART 4

# DENTISTS AND PROFESSIONS COMPLEMENTARY TO DENTISTRY CHAPTER 1

#### AMENDMENT OF THE DENTISTS ACT 1984

#### Introductory

**46.** The Dentists Act 1984(**b**) is amended in accordance with this Chapter.

## Amendment of section 15

- **47.**—(1) Section 15 (qualification for registration in the dentists register) is amended as follows.
- (2) In subsection (1)(ba)(i), for "3(9)(a) or (e)" substitute "3(8)(a) or (e)".
- (3) In subsection (1)(ba)(ii)—
  - (a) for "20 to 26" substitute "27 to 34";
  - (b) for "3(4)" substitute "3(5)".

<sup>(</sup>a) S.I. 2010/1617, which was amended by S.I. 2012/3171. There are other amendments which are not relevant to these Regulations.

**<sup>(</sup>b)** c. 24.

#### **Amendment of section 29**

- **48.**—(1) Section 29 (appeals)(a) is amended as follows.
- (2) In subsection (1)(b), omit the "and" at the end.
- (3) After subsection (1)(c), insert—
  - "(d) a decision of the Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (4) In subsection (1B) after "(10)," insert "or regulation 67 of the General Systems Regulations,".
- (5) In subsection (3)(b), after "against" insert "or, in the case of an appeal from a decision falling within subsection (1)(d), direct that the alert be withdrawn or amended".
  - (6) In subsection (3)(c), before "the Professional Conduct Committee" insert "the Council,".
  - (7) In subsection (3)(d), before "the Professional Conduct Committee" insert "the Council,".

#### Amendment of section 36S

- **49.**—(1) Section 36S (appeals)(**b**) is amended as follows.
- (2) In subsection (1)(b), omit the "and" at the end.
- (3) After subsection (1)(c), insert—
  - "(d) a decision of the Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (4) In subsection (3), after "(10)," insert "or regulation 67 of the General Systems Regulations,".
- (5) In subsection (6)(b), after "against" insert "or, in the case of an appeal from a decision falling within subsection (1)(d), direct that the alert be withdrawn or amended".
  - (6) In subsection (6)(c), before "the Professional Conduct Committee" insert "the Council,".
  - (7) In subsection (6)(d), before "the Professional Conduct Committee" insert "the Council,".

## Amendment of section 36Z3

- **50.**—(1) Section 36Z3 (visiting dental care professionals from relevant European States)(c) is amended as follows.
  - (2) In subsection (2), for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24"; and
    - (b) for "8" substitute "12".

## **Amendment of section 53**

- **51.**—(1) Section 53(1) (interpretation)(**d**) is amended as follows.
- (2) For the definition of "the General Systems Regulations", substitute—
  - ""the General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".
- (3) In the appropriate places, insert—

- (c) Section 36Z3 was inserted by S.I. 2007/3101.
- (d) Section 53(1) was amended by S.I. 1996/1496, 2005/2011, 2007/3101, 2011/1043 and 2015/806.

<sup>(</sup>a) Section 29 was amended by sections 31 and 37 of, and Schedules 8 and 9 to, the National Health Service Reform and Health Care Professions Act 2002 (c.17) and by S.I. 2005/2011.

**<sup>(</sup>b)** Section 36S was inserted by S.I. 2005/2011.

""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";

""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";

""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;".

#### Amendment of Schedule 2

- **52.**—(1) Schedule 2 (European dental qualifications) is amended as follows.
- (2) In paragraph 1(a)—
  - (a) the existing wording becomes sub-paragraph (1);
  - (b) after sub-paragraph (1), as so renumbered, insert—
    - "(2) References in this Schedule to article 34 of the Directive are, in relation to training begun on or before 18 January 2016, to article 34 disregarding the amendments made by Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013."
- (3) After paragraph 6A(b) insert—
  - "**6B.** A medical qualification as a doctor awarded in Spain to a person who began medical training at a university between 1 January 1986 and 31 December 1997 is an appropriate European diploma for the purposes of section 15(1)(b) where that person produces to the registrar a certificate issued by the competent authority in Spain certifying that—
    - (a) the person has successfully completed at least three years of study, certified by the competent authority in Spain, as being equivalent to the training referred to in article 34 of the Directive;
    - (b) the person has effectively, lawfully and principally practised dentistry in Spain for at least three consecutive years during the five years preceding the date of issue of the certificate; and
    - (c) the person is authorised to practise dentistry or is effectively, lawfully and principally engaged in dentistry under the same conditions as a holder of the qualifications listed in relation to Spain in Annex V, point 5.3.2 of the Directive.".

## **Amendment of Schedule 4**

- **53.**—(1) Schedule 4 (visiting dentists from relevant European States)(c) is amended as follows.
- (2) In paragraph 4(b)—
  - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e)";
  - (b) for "14 to 16" substitute "19 to 23".
- (3) In paragraph 5—
  - (a) in sub-paragraph (2)(a)—
    - (i) in sub-paragraph (i), omit the "and" at the end;
    - (ii) after sub-paragraph (ii), insert—

<sup>(</sup>a) Paragraph 1 was substituted by S.I. 2007/3101.

<sup>(</sup>b) Paragraph 6A was inserted by S.I. 2003/3148 and amended by 2007/3101.

<sup>(</sup>c) Schedule 4 was substituted by S.I. 2007/3101.

- "(iii) confirms that the practitioner does not have a criminal conviction; and
- (iv) confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a dentist;";
- (b) after sub-paragraph (2)(a), insert—
  - "(aa) a written declaration as to whether the practitioner has the necessary knowledge of English;";
- (c) in sub-paragraph (3), after "(2)(a)" insert "or (aa)".
- (4) In paragraph 6(3)—
  - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e)";
  - (b) for "14 to 16" substitute "19 to 23".
- (5) In paragraph 8(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a dental professional".

#### Amendment of Schedule 4ZA

- **54.**—(1) Schedule 4ZA (Directive 2005/36: functions of the Council under section 36ZA(3))(**a**) is amended as follows.
  - (2) Before the entry relating to article 7(2)(b) insert—

"Article 4f Considering applications for partial access to the dental professions under regulations 10 and 11 of the General Systems Regulations."

- (3) In the entry relating to article 8(1)—
  - (i) for "Receiving", substitute "In the event of justified doubts, receiving"; and
  - (ii) after paragraph (c), insert—

"Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.".

(4) After the entry relating to article 50(3), insert—

"Article 50(3a) In the event of justified doubts, seeking confirmation from, or providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the dental professions as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's professional activities.

Article 50(3b) Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI."

(5) In the entry relating to article 56(2), after paragraph (c) insert—

"Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI.".

(6) After the entry relating to article 56(2), insert—

"Article 56(2a) Ensuring that the exchange of information carried out in accordance with article 56(2) of the Directive takes place through the IMI.

Article 56a (1) Informing all other competent authorities, by way of an alert through and (2) the IMI, about a dentist or a dental care professional whose professional activities have been prohibited or restricted, even

temporarily, within three days from the date of the adoption of the decision; ensuring that the information provided is limited to the

<sup>(</sup>a) Schedule 4ZA was inserted by S.I. 2007/3101.

	information referred to in article 56a(2) of the Directive.
Article 56a(3)	Informing all other competent authorities, by way of an alert through
	the IMI, about the identity of professionals who have applied for
	registration and who have been subsequently found to have used
	falsified evidence of professional qualifications, within three days from
	the date of the finding.
Article 56a(4)	Ensuring that the processing of personal data for the purposes of the
	exchange of information under article 56a(1) and (3) of the Directive is
	carried out in accordance with Directive 95/46/EC and Directive
A	2002/58/EC.
Article 56a(5)	Informing all other competent authorities through the IMI without delay when—
	(a) a prohibition or a restriction referred to in article 56a(1) of the
	Directive has expired;
	(b) there is a change to the prohibition or restriction period notified
	under article 56a(2) of the Directive.
Article 56a(6)	Notifying the practitioner, in respect of whom an alert is sent under
	article 56a(1) or (3) of the Directive, in writing at the same time as the
	alert is sent, that the practitioner—
	(a) is the subject of an alert sent under article 56a(1) or (3) of the
	Directive;
	(b) has the right to appeal the decision or to apply for rectification of the decision;
	•
	(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.
	Informing competent authorities, where applicable, that an alert is the
	subject of appeal proceedings by the practitioner.
Article 56a(7)	Ensuring that an alert made under article 56a(1) of the Directive is
	deleted from the IMI within three days of—
	(a) the date of adoption of the revoking decision; or
	(b) the expiry of the prohibition or restriction referred to in that article.
Article 57a(1)	Ensuring that all requirements, procedures and formalities relating to
	the recognition of qualifications of a dentist or a dental care
	professional may be easily completed by the applicant remotely and by
	1

## **CHAPTER 2**

## AMENDMENT OF THE EUROPEAN PRIMARY AND SPECIALIST DENTAL QUALIFICATIONS REGULATIONS 1998

## Introductory

55. The European Primary and Specialist Dental Qualifications Regulations 1998(a) are amended in accordance with this Chapter.

## Amendment of regulation 2

**56.**—(1) Regulation 2(1) (interpretation)(**b**) is amended as follows.

electronic means."

(2) For the definition of "General Systems Regulations", substitute—

""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015;".

<sup>(</sup>a) S.I. 1998/811.

<sup>(</sup>b) Regulation 2(1) was amended by S.I. 2004/1947, 2007/3101 and 2011/1043.

(3) In the appropriate places, insert—

""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";

""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12th July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";

""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;".

## Amendment of regulation 7

- **57.**—(1) Regulation 7 (minimum requirements of specialist dental training)(**a**) is amended as follows.
  - (2) After paragraph (4), insert—

"(5) For the purposes of meeting the conditions specified in article 35 of the Directive under this regulation, the reference in article 35 of the Directive to article 34 of the Directive is, in relation to training begun on or before 18th January 2016, to article 34 disregarding the amendments made by Directive 2013/55/EU of the European Parliament and of the Council of 20th November 2013."

## Amendment of regulation 8

**58.**—(1) Regulation 8 (distinctive titles and specialist lists) is amended as follows.

- (2) In paragraph (2)(c)—
  - (a) for "3(9)(a) or (e)" substitute "3(8)(a) or (e)";
  - (b) for "20 to 26" substitute "19 to 23";
  - (c) for "3(4)" substitute "3(5)".

## **Insertion of regulation 15A**

**59.** In Part 2, after regulation 15 (revocation and saving)(**b**), insert—

#### "Review

**15A.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—

- (a) carry out a review of the amendments made to these Regulations by the European Qualifications (Health and Social Care Professions) Regulations 2016;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.".

<sup>(</sup>a) Regulation 7 was amended by S.I. 2007/3101, which substituted paragraphs (1) and (2) for paragraphs (1) to (3) as originally enacted.

**<sup>(</sup>b)** Regulation 16 was originally in Part 3 and was revoked by S.I. 2007/3101.

#### Amendment of Schedule A1

- **60.**—(1) Schedule A1 (Directive 2005/36: functions of the GDC under regulation 4(2))(a) is amended as follows.
  - (2) Before the entry relating to article 7(2)(b), insert—

"Article 4f Considering applications for partial access to the dental profession in the field of orthodontics or oral surgery under regulations 10 and 11 of the General Systems Regulations."

- (3) In the entry relating to article 8(1)—
  - (a) for "Receiving" substitute "In the event of justified doubts, receiving";
  - (b) after paragraph (c), insert—

"Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.".

- (4) After the entry relating to article 50(3), insert—
  - "Article 50(3a) In the event of justified doubts, seeking confirmation from, or providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the practice of orthodontics or oral surgery as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of any of the applicant's professional activities.
  - Article 50(3b) Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI."
- (5) In the entry relating to article 56(2), after paragraph (c) insert—

"Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI."

(6) After the entry relating to article 56(2) insert—

"Article 56(2a) Ensuring that the exchange of information carried out in accordance with article 56(2) of the Directive takes place through the IMI.

Article 56a(1) Informing all other competent authorities, by way of an alert through the IMI, about an orthodontist or oral surgeon whose professional activities have been prohibited or restricted, even temporarily, within three days from the date of the adoption of the decision; ensuring that the information provided is limited to the information referred to in article 56a(2) of the Directive.

Article 56a(3) Informing all other competent authorities, by way of an alert through the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications, within three days from the date of the finding.

Ensuring that the processing of personal data for the purposes of the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with Directive 95/46/EC and Directive

2002/58/EC.

Article 56a(5) Informing all other competent authorities through the IMI without

delay when-

(a) a prohibition or a restriction referred to in article 56a(1) of the

Directive has expired;

(b) there is a change to the prohibition or restriction period notified

Article 56a(4)

<sup>(</sup>a) Schedule A1 was inserted by S.I. 2007/3101.

under article 56a(2) of the Directive.

Article 56a(6)

Notifying the orthodontist or oral surgeon, in respect of whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the orthodontist or oral surgeon—
(a) is the subject of an alert sent under article 56a(1) or (3) of the Directive;

(b) has the right to appeal against the decision or to apply for rectification of the decision;

(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.

Informing competent authorities, where applicable, that an alert is the subject of appeal proceedings by the orthodontist or oral surgeon.

Article 56a(7)

Ensuring that an alert made under article 56a(1) of the Directive is

deleted from the IMI within three days of-

(a) the date of adoption of the revoking decision; or

(b) the expiry of the prohibition or restriction referred to in that article.

Article 57a(1)

Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications as an orthodontist or oral surgeon may be easily completed by the applicant remotely and by electronic means."

## PART 5

## NURSES AND MIDWIVES

#### CHAPTER 1

## AMENDMENT OF THE NURSING AND MIDWIFERY ORDER 2001

## Introductory

**61.** The Nursing and Midwifery Order 2001(a) is amended in accordance with this Chapter.

#### Amendment of article 13

- **62.**—(1) Article 13 (approved qualifications)(**b**) is amended as follows.
- (2) In paragraph (1)(e)(i), for "3(9)" substitute "3(8)".
- (3) In paragraph (1)(e)(ii)—
  - (a) for "20 to 26" substitute "27 to 34";
  - (b) for "3(4)" substitute "3(5)".

#### Amendment of article 37

- **63.**—(1) Article 37 (appeals against Registrar's decisions)(**c**) is amended as follows.
- (2) In paragraph (1)—
  - (a) after "the Registrar", where the words first appear, insert "or the Council";
  - (b) omit "under this Order";
  - (c) in sub-paragraph (c), omit the "or" at the end;

<sup>(</sup>a) S.I. 2002/253.

<sup>(</sup>b) There are amendments to article 13, but none are relevant to these Regulations.

<sup>(</sup>c) Article 37 was amended by S.I. 2007/3101, 2014/1887 and 2015/806. There are other amendments but these are not relevant to these Regulations.

- (d) after sub-paragraph (d) insert—
  - "(e) requires an exempt person to complete an adaptation period, or pass an aptitude test, in connection with the person's entitlement to have access to, and to pursue, the profession of nurse or midwife in the United Kingdom, under Part 3 of the General Systems Regulations;
  - (f) decides to send an alert about a person under regulation 67 of the General Systems Regulations;
  - (g) decides to revoke a European professional card, or not to issue, extend or vary a European professional card, under Schedule 2B or under Part 4 of the General Systems Regulations; or
  - (h) fails to make a decision in relation to a European professional card within the time limit under paragraph 10(4) or 12(4) of Schedule 2B or regulation 51(1) or 56(1) of the General Systems Regulations,".
- (3) In paragraph (9)(b), after "against" insert "or, in the case of an appeal under paragraph (1)(f), direct that the alert be withdrawn or amended".
  - (4) In paragraph (9)(c), omit the "or" at the end.
  - (5) After paragraph (9)(c), insert—
    - "(ca) with respect to an appeal under paragraph (1)(h), enter any decision which could have been taken by the Council; or".

## **Amendment of article 38**

- **64.**—(1) Article 38 (appeals)(**a**) is amended as follows.
- (2) Omit paragraph (1A)(b).
- (3) In paragraph (3)(b), after "against" insert "or, in the case of an appeal under article 37(1)(f), direct that the alert be withdrawn or amended".
  - (4) In paragraph (3)(c), omit the "or" at the end.
  - (5) After paragraph (3)(c), insert—
    - "(ca) with respect to an appeal under paragraph (1)(h), enter any decision which could have been taken by the Council; or".

### Amendment of article 39A

- **65.**—(1) Article 39A (visiting general systems nurses from relevant European States)(**b**) is amended as follows.
  - (2) In paragraph (2), for "8" substitute "12".
  - (3) In paragraph (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

#### Insertion of article 39B

66. After article 39A, insert—

### "European professional card

**39B.**—(1) Schedule 2B of this Order (Directive 2005/36/EC: European professional card) has effect.

<sup>(</sup>a) Article 38 was amended by S.I. 2007/3101.

**<sup>(</sup>b)** Article 39A was inserted by S.I. 2007/3101.

(2) The Council may charge a reasonable fee to cover the costs of processing an application for or in relation to a European professional card under Schedule 2B.".

#### **Insertion of article 55**

**67.** After article 54 (supplementary and transitional provisions and extent), insert—

#### "Review

- **55.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to this Order by the European Qualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

#### Amendment of Schedule 2A

- **68.**—(1) Schedule 2A (visiting midwives, and certain visiting nurses, from relevant European States)(a) is amended as follows.
- (2) In paragraph 1(a), after "United Kingdom" insert "and who is not a person to whom paragraph 15 of Schedule 2B (European professional card and entitlement to registration: provision of occasional nursing services) applies".
  - (3) In paragraph 4(b)—
    - (a) for "3(9)" substitute "3(8)";
    - (b) for "14 to 16" substitute "19 to 23".
  - (4) In paragraph 5, for sub-paragraph (2)(a), substitute—
    - "(a) a written declaration—
      - (i) that states the practitioner's wish to provide occasional nursing services or occasional midwifery services;
      - (ii) that contains details of any insurance cover or other means of personal or collective protection with regard to professional liability;
      - (iii) as to whether the practitioner has the necessary knowledge of English;
      - (iv) which confirms that the practitioner does not have a criminal conviction; and
      - (v) which confirms that the practitioner is not subject to a temporary or final suspension preventing practice as a nurse or midwife;".
  - (5) In paragraph 6(2)—
    - (a) for "3(9)" substitute "3(8)";
    - (b) for "14 to 16" substitute "19 to 23".
- (6) In paragraph 8(6), after "home State" insert "or, if different, a relevant European State in which the practitioner practises or has practised as a nurse".

## **Insertion of Schedule 2B**

69. After Schedule 2A, insert—

<sup>(</sup>a) Schedule 2A was inserted by S.I. 2007/3101.

## Directive 2005/36/EC: European professional card

## PART 1

#### General

### Introductory

**1.** This Schedule supplements the rights and obligations set out in the Implementing Regulation 2015.

## Interpretation

#### 2. In this Schedule—

"automatically recognised nurse" means a person who is entitled to have his or her qualifications as a nurse automatically recognised under articles 21, 23, 49a or 49b of the Directive:

"disqualifying decision" means a decision made by a competent authority or a judicial authority in a person's home State or host State that has the effect that—

- (a) the person ceases to be registered or otherwise officially recognised as a nurse in that State; or
- (b) the person is prohibited, permanently or temporarily, from practising as a nurse in that State;

"EPC applicant" means a person making, or who has made, an EPC application;

"EPC application" means an application for a European professional card made by a person who is seeking to practise as an automatically recognised nurse;

"EPC holder" means a person who holds a valid European professional card as a result of an EPC application;

"home State" means the relevant European State specified by an EPC applicant in his or her EPC application in accordance with article 4 of the Implementing Regulation 2015;

"host State" means the relevant European State in which an EPC applicant seeks to practise as a nurse;

"Implementing Regulation 2015" means Commission Implementing Regulation (EU) No 983 of 2015 on the procedure for issuance of the European professional card and the application of the alert mechanism pursuant to the Directive;

"missing document" means a document which an EPC applicant was required to provide with the EPC application but which the EPC applicant has not provided;

"nurse" means a nurse responsible for general care; and

"occasional nursing services" means the provision of services as a nurse on a temporary and occasional basis.

## PART 2

General functions of the Council in relation to European professional cards

## Council not to request resubmission of valid documents

**3.** If a person ("P") who has already made an application for or in relation to a European professional card makes a subsequent or further application for or in relation to a European

professional card, the Council may not request resubmission of documents that are contained in P's IMI file and which are still valid for the purposes of processing P's subsequent or further application.

## Power to revoke a European professional card

- **4.**—(1) The Council may revoke a European professional card issued under this Schedule if it appears to the Council that the person ("P") to whom the card was issued is not entitled to hold the card.
- (2) P is not entitled to hold a European professional card if, in particular, P is subject to a disqualifying decision.

## Rectification of the European professional card or the IMI file

- **5.**—(1) If an automatically recognised nurse ("P") holds a European professional card issued by the Council, P may, at any time, make a written request to the Council to rectify inaccurate or incomplete data in P's IMI file or to delete or block P's IMI file if it contains inaccurate or incomplete data.
- (2) If the Council is satisfied that the data in P's IMI file is inaccurate or incomplete, the Council must comply with a request by P under sub-paragraph (1).
  - (3) The Council must notify P of P's right under sub-paragraph (1)—
    - (a) at the time P's European professional card is issued;
    - (b) within the period ending two years after the date on which the European professional card was issued; and
    - (c) subsequently at intervals not exceeding two years from the date of the previous notification.
- (4) A notification under sub-paragraph (3)(b) or (c) must be sent to P by means of an automatic reminder sent through the IMI.
- (5) The Council must not charge P a fee in relation to the making of a written request under sub-paragraph (1) or in relation to complying with, or responding to, such a request.
  - (6) If—
    - (a) P's European professional card was issued for the purposes of establishment;
    - (b) P asks the Council to delete P's IMI file; and
    - (c) P's host State is the United Kingdom,

the Council must provide P with evidence confirming that the Council recognises P's professional qualifications.

## Duty to give reasons and to notify of right of appeal

**6.** If the Council refuses to issue, extend or vary, or decides to revoke, a European professional card under this Schedule, the Council must notify the EPC applicant or the EPC holder of the reasons for that decision and of his or her right of appeal under article 37.

## Updating the IMI file: disciplinary actions or criminal sanctions

- 7.—(1) This paragraph applies if a person ("P")—
  - (a) makes an EPC application to the Council; or
  - (b) is an EPC holder and P's European professional card was issued by the Council.
- (2) The Council must update P's IMI file in accordance with sub-paragraphs (3) and (4) in a timely manner.
- (3) The Council must add to P's IMI file information, regarding disciplinary action or criminal sanctions, which—

- (a) relates to a prohibition or restriction on P's entitlement to practise as a nurse; or
- (b) has consequences for the pursuit of any activities by P, in P's capacity as a nurse.
- (4) The Council must delete from P's IMI file information regarding disciplinary action or criminal sanctions that is no longer required.
- (5) The Council must immediately inform P and the competent authorities of other relevant European States that have access to P's IMI file of any update under this paragraph.
- (6) The information that may be added or deleted under this paragraph must be limited to details of—
  - (a) P's identity;
  - (b) information about the national authority or court which has made a decision on a restriction or prohibition applying to P;
  - (c) the scope of the restriction or prohibition; and
  - (d) the period for which the restriction or prohibition applies.

#### Access to data

- **8.**—(1) The Council may access information on the IMI file of an EPC applicant or an EPC holder, in accordance with Directive 95/46/EC, only if the United Kingdom is the home State or the host State of the applicant or the holder.
- (2) The Council must provide an EPC applicant or an EPC holder with information on the content of his or her IMI file on request.

## **Processing data**

- **9.**—(1) The Council may process personal data to which it has access under paragraph 8—
  - (a) for as long as it is needed for the purposes of recognition of the professional qualifications of the EPC applicant or the EPC holder; and
  - (b) as evidence of the recognition or transmission of the declaration required as part of the documents submitted under paragraph 12(2).
- (2) The Council is the controller within the meaning of article 2(d) of Directive 95/46/EC for the purposes of processing personal data in a person's European professional card or IMI file.

## PART 3

European professional cards for establishment in the United Kingdom or another relevant European State

## European professional cards for establishment in a host State other than the United Kingdom

- **10.**—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Council for the purposes of establishment as a nurse in a relevant European State other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the appropriate documents listed in paragraph 1 of Part A of Annex 2 to the Implementing Regulation 2015 (in addition to the information

required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).

- (3) Within the period of one week beginning with the date on which it receives the EPC application, the Council must acknowledge receipt of the application and inform P of any missing document.
  - (4) The Council must, within the period of one month beginning with the relevant day—
    - (a) decide whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised nurse; and
    - (b) transmit its decision (under paragraph (a)) and the EPC application to the competent authority of P's host State (in order for that competent authority to decide whether to issue the European professional card: see article 4d(2) of the Directive) and, at the same time, inform P of the status of the application.
  - (5) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Council receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Council.
  - (6) For the purpose of sub-paragraph (5), "relevant document" means—
    - (a) any previously missing document; or
    - (b) any document that is requested by the Council in connection with the EPC application before the day described in sub-paragraph (5)(a).

## Issue of European professional card for establishment in the United Kingdom

- 11.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to a competent authority of a relevant European State other than the United Kingdom for the purposes of establishment as a nurse in the United Kingdom;
  - (b) P's home State is not the United Kingdom;
  - (c) the competent authority of P's home State has decided whether the documents in P's IMI file are authentic and valid for the purposes of the EPC application and whether P is qualified as an automatically recognised nurse; and
  - (d) the competent authority of P's home State transmits the decision described in paragraph (c) and the EPC application to the Council (in order for the Council to decide whether to issue the European professional card: see article 4d(2) of the Directive).
- (2) The Council may request additional information or a certified copy of a document from the competent authority of P's home State if it appears to the Council—
  - (a) that the applicant may not be entitled to hold a European professional card in accordance with this Schedule; or
  - (b) that a document or information supplied as part of the EPC application is not, or may not be, valid or correct.
- (3) Subject to sub-paragraphs (4) to (6), the Council must issue the European professional card within one month of receipt of the EPC application from the competent authority of P's home State.
  - (4) The Council may extend the period in sub-paragraph (3)—
    - (a) by two weeks; and
    - (b) if considers it necessary to do so, in particular for reasons relating to public health or the safety of recipients or prospective recipients of nursing services from the

- EPC applicant, by a further two weeks following expiry of the two week extension under paragraph (a).
- (5) The Council must notify the applicant of any extension under sub-paragraph (4) and the reasons for it.
- (6) If the Council does not receive the documents or information necessary to determine whether to issue the European professional card, the Council may refuse to issue the card (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (7) If the Council fails to make a decision within the time limits set out in this paragraph—
  - (a) the applicant is to be treated as entitled to the European professional card; and
  - (b) the Council must issue the card to the applicant through the IMI immediately.

## PART 4

European professional cards for the provision of occasional nursing services in a relevant European State other than the United Kingdom

## Issue of European professional card for the provision of occasional nursing services in a host State other than the United Kingdom

- 12.—(1) This paragraph applies if—
  - (a) a person ("P") makes an EPC application to the Council for the purposes of providing occasional nursing services (which do not fall within article 7(4) of the Directive) in one or more relevant European States other than the United Kingdom; and
  - (b) P's home State is the United Kingdom.
- (2) P must submit with the EPC application the documents listed in paragraphs (a) to (c) of Part B of Annex 2 to the Implementing Regulation 2015 (in addition to the information required in accordance with article 4 of the Implementing Regulation 2015 that is relevant to the application).
- (3) Within the period of one week beginning with the date on which the Council receives the EPC application, the Council must acknowledge receipt of the application and inform P of any missing document.
  - (4) The Council must within three weeks of the relevant day—
    - (a) consider P's EPC application, the authenticity and validity of the supporting documents and whether P is qualified as an automatically recognised nurse;
    - (b) decide whether to approve or refuse the application and whether to issue the European professional card; and
    - (c) transmit its decision (under paragraph (b)) and, if issued, the European professional card, to the competent authority of each host State concerned and, at the same time, inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
- (5) Unless its period of validity is extended under paragraph 13, a European professional card issued under this paragraph expires 18 months after the date on which it is issued.
  - (6) In this paragraph, "the relevant day" means the later of—
    - (a) the day which falls one week after the day on which the Council receives the EPC application; or
    - (b) the day on which the last relevant document is received by the Council.
  - (7) For the purpose of sub-paragraph (6), "relevant document" means—
    - (a) any previously missing document; or

(b) any document that is requested by the Council in connection with the EPC application before the day described in sub-paragraph (6)(a).

## Variation of a European professional card for the provision of occasional nursing services in a host State other than the United Kingdom

- **13.**—(1) This paragraph applies to an automatically recognised nurse ("P") who holds a European professional card issued under paragraph 12.
- (2) If P wishes to provide relevant nursing services after the end of the period of 18 months beginning with the date on which the card was issued, P may apply to the Council for the period of validity of the card to be extended by 18 months or such shorter period as may be specified in the application.
- (3) If P wishes to provide relevant nursing services in a host State not already specified on the card, P may apply to the Council for the list of host States specified on the card to be supplemented with the addition of such relevant European States as may be specified in the application.
- (4) An application under sub-paragraph (2) or (3) must be accompanied by details of any material changes to documentation or information that—
  - (a) was, pursuant to the Implementing Regulation 2015, provided to the Council with the EPC application under paragraph 12; and
  - (b) is recorded in P's IMI file.
  - (5) After considering an application under sub-paragraph (2) or (3), the Council must—
    - (a) accept the application (see sub-paragraph (6)); or
    - (b) if it appears to the Council that P is not, or may not be, entitled to hold a European professional card, reject the application and inform P of its decision (also see paragraph 6: duty to give reasons and to notify of right of appeal).
  - (6) If the Council accepts the application, the Council must—
    - (a) issue an amended European professional card;
    - (b) transmit the card to the competent authority of each host State specified on the card; and
    - (c) notify P.
- (7) In this paragraph, "relevant nursing services" means occasional nursing services that are provided or to be provided in a relevant European State other than the United Kingdom.

#### PART 5

European professional card: requirements and entitlements as to registration

## Requirement to register: establishment cases

- **14.**—(1) A person ("P") who holds a valid European professional card for establishment in the United Kingdom is not entitled to practise as a nurse in the United Kingdom on the basis of establishment unless P complies with any requirements of, or under, this Order as to registration in the United Kingdom on that basis.
- (2) For the purposes of registration, P is not required to resubmit any document or evidence which is contained in P's IMI file and which is still valid.

## Entitlement to registration: provision of occasional nursing services

**15.**—(1) This paragraph applies to a person ("P") who holds a valid European professional card, in relation to the provision of occasional nursing services in the United Kingdom, which—

- (a) has been transmitted to the Council through the IMI by the competent authority of P's home State (pursuant to article 4c of the Directive); or
- (b) has been issued by the Council under regulation 52 of the General Systems Regulations.
- (2) Subject to sub-paragraphs (3) to (6)—
  - (a) P is entitled to be entered in the register and the Council must give effect to that entitlement; and
  - (b) if P is not entered in the register, P is treated as being so entered.
- (3) If P's European professional card has been issued by the Council under regulation 52 of the General Systems Regulations, P's entitlement to be entered in the register ceases at the end of the period of 12 months beginning with the date on which the Council issued P's card.
  - (4) This sub-paragraph applies if—
    - (a) P's European professional card is, or becomes, invalid;
    - (b) P is subject to a disqualifying decision; or
    - (c) P becomes established as a nurse in the United Kingdom.
  - (5) If sub-paragraph (4) applies—
    - (a) the Council may refuse to enter P in, or may remove P from, the register; and
    - (b) sub-paragraph (2) ceases to apply.
- (6) This paragraph is without prejudice to any other provision of this Order under which the name of a registered nurse may be removed from the register or under which the registration of a registered nurse may be suspended.

## PART 6

## Conditions in relation to fitness to practise

## Conditions in relation to fitness to practise: providers of occasional nursing services

16.—(1) Sub-paragraph (2) applies in relation to a person ("P") who—

- (a) falls within paragraph 15(1); and
- (b) is entered in the register.
- (2) If it falls to be decided whether P's fitness to practise is or may be impaired on the ground of misconduct for any of the purposes of this Order, then "misconduct" includes any act or omission by P during the course of P's provision of occasional nursing services—
  - (a) which constitutes a breach of a condition or limitation to which P is subject in relation to P's practice as a nurse in P's home State; or
  - (b) which would constitute a breach of the condition or limitation mentioned in paragraph (a) if that condition or limitation applied in relation to P's practice as a nurse outside of P's home State.".

## Amendment of Schedule 3

- **70.**—(1) Schedule 3 (Directive 2005/36: Functions of the Council under article 40(2))(**a**) is amended as follows.
  - (2) Before the entry relating to article 7(2)(b), insert—
    - "Article 4a Ensuring that the holder of a European professional card benefits

<sup>(</sup>a) Schedule 3 was substituted by S.I. 2007/3101 and amended by 2015/806.

from all of the rights conferred by articles 4b to 4e of the Directive.

Charging reasonable fees to cover the costs of processing applications for or in relation to European professional cards under Schedule 2B and under Part 4 of the General Systems

Regulations.

Article 4b Enabling nurses responsible for general care to apply for a

European professional card in accordance with Schedule 2B and in accordance with Part 4 of the General Systems Regulations.

Article 4c Verifying the application and supporting documents in the IMI

file and issuing the European professional card for nurses responsible for general care for the temporary and occasional provision of nursing services other than those covered by article

7(4) of the Directive.

Article 4d Verifying the authenticity and validity of the application and

supporting documents in the IMI file for the purpose of issuing the European professional card for nurses responsible for general care for establishment or for the temporary and occasional provision of nursing services under article 7(4) of the Directive.

Article 4e Updating, in a timely manner, the IMI file of a holder of a

European professional card with information about disciplinary actions or criminal sanctions regarding a prohibition or restriction and which have consequences for the pursuit of any professional activities by that person the under the Directive. Considering applications for partial access to the profession of

Considering applications for partial access to the profession of

nursing and midwifery under regulations 10 and 11 of the

General Systems Regulations."

(3) In the entry relating to article 8(1)—

Article 4f

(a) for "Receiving" substitute "In the event of justified doubts, receiving";

(b) after paragraph (c), insert—

"Receiving information from, or providing information to, other competent authorities in relation to a person's training courses to the extent necessary to assess substantial differences likely to be harmful to public health and safety.".

(4) After the entry relating to article 50(3), insert—

"Article 50(3a) In the event of justified doubts, seeking confirmation from, or

providing confirmation to, other competent authorities of the fact that the applicant is not suspended or prohibited from the pursuit of the profession of nursing and midwifery as a result of serious professional misconduct or conviction of criminal offences relating to the pursuit of

any of the applicant's professional activities.

Article 50(3b) Ensuring that the exchange of information under article 50 of the

Directive with other competent authorities takes place through

the IMI."

(5) In the entry relating to article 56(2), after paragraph (c), insert—

"Ensuring that the processing of personal data for the purposes of the exchange of information in accordance with article 56(2) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI.".

(6) After the entry relating to article 56(2), insert—

"Article 56(2a) Ensuring that the exchange of information carried out in accordance

with article 56(2) of the Directive takes place through the IMI.

Article 56a (1) Informing all other competent authorities, by way of an alert through and (2) the IMI, about a nurse or midwife whose professional activities have

been restricted or prohibited, even temporarily, within three days from

the date of adoption of the decision; ensuring the information provided is limited to the information referred to in article 56a(2) of the Directive.

Article 56a(3) Informing all other competent authorities, by way of an alert through the IMI, about the identity of professionals who have applied for registration and who have been subsequently found to have used falsified evidence of professional qualifications, within three days from the date of the finding.

Article 56a(4) Ensuring that the processing of personal data for the purposes of the exchange of information under article 56a(1) and (3) of the Directive is carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC.

Article 56a(5) Informing all other competent authorities through the IMI without delay when—

(a) a prohibition or a restriction referred to in article 56a(1) of the Directive has expired;

(b) there is a change to the prohibition period notified under article 56a(2) of the Directive.

Article 56a(6) Notifying the nurse or midwife, in respect of whom an alert is sent under article 56a(1) or (3) of the Directive, in writing at the same time as the alert is sent, that the nurse or midwife—

(a) is the subject of an alert sent under article 56a(1) or (3) of the Directive;

(b) has the right to appeal the decision or to apply for rectification of the decision;

(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.

Informing competent authorities, where applicable, that an alert is the subject of appeal proceedings by the nurse or midwife.

Article 56a(7) Ensuring that an alert made under article 56a(1) of the Directive is deleted from the IMI within three days of—

(a) the date of adoption of the revoking decision; or

(b) the expiry of the prohibition or restriction referred to in that article.

Article 57a(1) Ensuring that all requirements, procedures and formalities relating to the recognition of qualifications as a nurse or a midwife may be easily completed by the applicant remotely and by electronic means."

## Amendment of Schedule 4

71.—(1) Schedule 4 (interpretation)(a) is amended as follows.

(2) For the definition of "General Systems Regulations" substitute—

""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015;".

(3) In the appropriate places, insert—

""Directive 95/46/EC" means Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, as amended from time to time;";

""Directive 2002/58/EC" means Directive 2002/58/EC of the European Parliament and of the Council of 12th July 2002 concerning the processing of personal data and the

<sup>(</sup>a) Schedule 4 was amended by S.I. 2002/2469, 2003/3148, 2004/1947, 2007/3101, 2008/1485, 2011/1043, 2014/1887, 2015/806 and by S.R. (N.I.) 2009 No. 144.

protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), as amended from time to time;";

""European professional card" has the meaning given in the Directive;";

""IMI" means the Internal Market Information System, the online, secure messaging system developed by the European Commission;";

""IMI file" means a secure personal account in the IMI that is created in relation to an applicant for a European professional card by means of an online tool provided by the European Commission;".

#### **CHAPTER 2**

## AMENDMENT OF THE EUROPEAN NURSING AND MIDWIFERY QUALIFICATIONS DESIGNATION ORDER OF COUNCIL 2004

#### Introductory

72. The European Nursing and Midwifery Qualifications Designation Order of Council 2004(a) is amended in accordance with this Chapter.

#### Amendment of article 2

- **73.**—(1) Article 2 (interpretation)(**b**) is amended as follows.
- (2) In paragraph (3), for "41(1)(a)(ii) or (c)" substitute "41(1)(a) or (c)".

#### Amendment of article 3

- 74.—(1) Article 3 (qualifications in respect of which a listed diploma is awarded on or after the reference date)(c) is amended as follows.
  - (2) In paragraph (2)(b), for "(1)(a)(ii) or (c)" substitute "(1)(a) or (c)".

#### Amendment of article 4

- 75.—(1) Article 4 (qualifications in respect of which a listed diploma is awarded before the reference date)(d) is amended as follows.
  - (2) In paragraph (1), omit "Poland or".
  - (3) In paragraph (3)(b), for "(1)(a)(ii) or (c)" substitute "(1)(a) or (c)".

### Amendment of article 5

- 76.—(1) Article 5 (qualifications in respect of which a diploma other than a listed diploma is awarded before the reference date in respect of training which does not comply with Directive requirements)(e) is amended as follows.
  - (2) In paragraph (1), omit "Poland or".

## Amendment of article 6

77.—(1) Article 6 (qualifications in respect of which a diploma other than a listed diploma is awarded in respect of training which complies with Directive requirements)(f) is amended as follows.

<sup>(</sup>a) S.I. 2004/1766.

**<sup>(</sup>b)** Article 2 was amended by S.I. 2007/3101.

<sup>(</sup>c) Article 3 was substituted by S.I. 2007/3101. (d) Article 4 was substituted by S.I. 2007/3101.

<sup>(</sup>e) Article 5(1) was substituted by S.I. 2007/3101.

<sup>(</sup>f) Article 6 was substituted by S.I. 2007/3101.

(2) In paragraph (3)(b), for "(1)(a)(ii) or (c)" substitute "(1)(a) or (c)".

#### Amendment of article 7

- **78.**—(1) Article 7 (qualifications awarded in Poland before the reference date in respect of training which does not comply with Directive requirements)(a) is amended as follows.
  - (2) In paragraph (2), omit sub-paragraph (a).
  - (3) Omit paragraph (3).

#### Amendment of article 7A

- **79.**—(1) Article 7A (qualifications awarded in Romania before the reference date in respect of training which does not comply with Directive requirements)(**b**) is amended as follows.
  - (2) In paragraph (2), for sub-paragraph (a) substitute—
    - "(a) in the case of a person holding evidence of one of the following formal qualifications as a nurse—
      - (i) competențe profesionale de asistent medical generalist, with post-secondary education obtained from a școli postliceale, attesting to training started before 1st January 2007;
      - (ii) diplomă de absolvire de asistent medical generalist cu studii superioare de scurtă durată, attesting to training started before 1st October 2003;
      - (iii) diplomă de licență de asistent medical generalist cu studii superioare de lungă durată, attesting to training started before 1st October 2003,

at least three consecutive years during the period of five years ending with the date of issue of the certificate, provided that the period of practice has included the person taking full responsibility for the planning, organisation and carrying out of nursing care of patients; or".

#### **Insertion of article 8A**

**80.** After article 8 (qualifications in midwifery awarded following training in the former German Democratic Republic which complies with Directive requirements)(**c**), insert—

## "Qualifications in midwifery awarded in respect of training which started before 18th January 2016

- **8A.**—(1) A diploma in midwifery which has been awarded in a relevant European State and which was started before 18th January 2016 is an approved qualification for the purposes of registration if one of the conditions in paragraph (2) is satisfied.
  - (2) The conditions are—
    - (a) the admission requirement for starting the diploma was 10 years of general education;
    - (b) the diploma was equivalent to specific full time training as a midwife, comprising at least three years of theoretical and practical study comprising at least the training programme described in Annex V, point 5.5.1 of the Directive; or
    - (c) the diploma was equivalent to at least 18 months specific full time training as a midwife comprising at least the training programme described in Annex V, point 5.5.1 of the Directive and, before starting that diploma, the applicant completed training as a nurse responsible for general care and, in respect of that training as a

<sup>(</sup>a) Article 7 was substituted in part, and amended, by S.I. 2007/3101.

<sup>(</sup>b) Article 7A was inserted by S.I. 2007/3101.

<sup>(</sup>c) Article 8 was substituted by S.I. 2007/3101.

nurse responsible for general care, can produce evidence that he or she holds a diploma that is listed in Annex V, point 5.2.2 of the Directive.".

#### **Insertion of article 12**

**81.** After article 10 (qualifications following training in the former Czechoslovakia, etc.)(a), insert—

## "Review

- **12.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to this Order by the European Qualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

#### **CHAPTER 3**

AMENDMENT OF THE NURSING AND MIDWIFERY COUNCIL (EDUCATION, REGISTRATION AND REGISTRATION APPEALS) RULES ORDER OF COUNCIL 2004

## Introductory

**82.** The Nursing and Midwifery (Education, Registration and Registration Appeals) Rules 2004, which are set out in the Schedule to the Nursing and Midwifery Council (Education, Registration and Registration Appeals) Rules Order of Council 2004(**b**), are amended in accordance with this Chapter.

### Amendment of rule 5

- **83.**—(1) Rule 5 (application for admission to a part of the register)(c) is amended as follows.
- (2) In paragraph (2)(a)(ii), before "the certificate" insert "a valid European professional card as a nurse or".
- (3) In paragraph (2)(a)(iv), before "evidence" insert "a valid European professional card as a nurse or".
  - (4) After paragraph (4), insert—
    - "(4A) The requirement to provide a certificate under paragraph (3) does not apply where the applicant holds a valid European professional card as a nurse.".

## Amendment of rule 20

- **84.**—(1) Rule 20 (period during which an appeal may be made)(**d**) is amended as follows.
- (2) In paragraph (a)—
  - (a) for "or (c)" substitute ", (c) or (e) to (h)";
  - (b) omit the "or" at the end.
- (3) In paragraph (b), at the end, insert "; or".
- (4) After paragraph (b), insert—

<sup>(</sup>a) Article 11 was revoked by S.I. 2007/3101.

**<sup>(</sup>b)** S.I. 2004/1767.

<sup>(</sup>c) Rule 5 was amended by S.I. 2007/3101, 2014/1887 and 2015/1923.

<sup>(</sup>d) Rule 20 was amended by S.I. 2007/3101 and 2015/1923.

"(c) where the appeal is in relation to a failure to issue a decision in relation to a European professional card within the applicable time limit, as referred to in subparagraph (h) of that article, before the end of the period of 28 days beginning with the date by which the decision was required to have been sent."

### Amendment of rule 21

- **85.**—(1) Rule 21 (notice of appeal)(a) is amended as follows.
- (2) In paragraph (2)(a)(iii), for "or (c)" substitute ", (c) or (e) to (g)".
- (3) In paragraph (2)(a)(iv), after "37(1)(d)" insert "or (h)".

## PART 6

## OPTICIANS, OSTEOPATHS AND CHIROPRACTORS

## CHAPTER 1

## AMENDMENT OF THE OPTICIANS ACT 1989

#### Introductory

**86.** The Opticians Act 1989(**b**) is amended in accordance with this Chapter.

#### **Amendment of section 8C**

- 87.—(1) Section 8C (visiting optometrists: entitlement to registration)(c) is amended as follows.
- (2) In subsection (2), for "8" substitute "12".
- (3) In subsection (5)—
  - (a) for "17" substitute "24";
  - (b) for "8" substitute "12".

### **Amendment of section 8D**

- **88.**—(1) Section 8D (visiting dispensing opticians: entitlement to registration)(**d**) is amended as follows.
  - (2) In subsection (2), for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24;
    - (b) for "8" substitute "12".

## Amendment of section 23G

- **89.**—(1) Section 23G (appeals from the Registration Appeals Committee and the Fitness to Practise Committee)(e) is amended as follows.
  - (2) In subsection (1)(c), omit the "and" at the end.
  - (3) In subsection (1)(d), at the end insert "; and".

<sup>(</sup>a) Rule 21 was amended by S.I. 2015/1923.

**<sup>(</sup>b)** c. 44.

<sup>(</sup>c) Section 8C was inserted by S.I. 2007/3101.

<sup>(</sup>d) Section 8D was inserted by S.I. 2007/3101.

<sup>(</sup>e) Section 23G was inserted by S.I. 2005/848 and amended by section 99 of, and Schedule 7 to, the Health and Social Care Act 2008.

- (4) In subsection (1), after paragraph (d), insert—
  - "(e) a decision of the Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (5) In subsection (4)(b), for ", (c) or (d)" substitute "to (e)".
- (6) In subsection (4)(c), for ", (c) or (d)" substitute "to (e)".
- (7) After subsection (7), insert—
  - "(8) On an appeal under this section from a decision falling within subsection (1)(e), the relevant court may—
    - (a) dismiss the appeal; or
  - (b) allow the appeal and direct that the alert be withdrawn or amended, and may make such order for costs (or, in Scotland, expenses) as it (or the sheriff) thinks fit.

#### Amendment of section 36

- **90.**—(1) Section 36(1) (interpretation)(**a**) is amended as follows.
- (2) For the definition of "General Systems Regulations", substitute—

""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

### **CHAPTER 2**

## AMENDMENT OF THE OSTEOPATHS ACT 1993

## Introductory

**91.** The Osteopaths Act 1993(**b**) is amended in accordance with this Chapter.

66

<sup>(</sup>a) Section 36(1) was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

**<sup>(</sup>b)** c. 21.

#### Amendment of section 5A

- **92.**—(1) Section 5A (temporary registration for visiting osteopaths from relevant European States)(a) is amended as follows.
  - (2) In subsection (2), for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

#### Amendment of section 29A

- 93.—(1) Section 29A (appeals against decisions of the General Council)(b) is amended as follows.
  - (2) In subsection (2), after paragraph (b), insert—
    - "(c) a decision of the General Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (3) In subsection (3)(b), after "against" insert "or, in the case of an appeal from a decision falling within subsection (2)(c), direct that the alert be withdrawn or amended".

#### **Amendment of section 41**

- **94.**—(1) Section 41 (interpretation)(c) is amended as follows.
- (2) For the definition of "the General Systems Regulations", substitute—

""the General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

## **CHAPTER 3**

#### AMENDMENT OF THE CHIROPRACTORS ACT 1994

## Introductory

**95.** The Chiropractors Act 1994(**d**) is amended in accordance with this Chapter.

## Amendment of section 5A

- **96.**—(1) Section 5A (temporary registration for visiting chiropractors from relevant European States)(**e**) is amended as follows.
  - (2) In subsection (2) for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

<sup>(</sup>a) Section 5A was inserted by S.I. 2007/3101.

<sup>(</sup>b) Section 29A was inserted by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>c) Section 41 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>**d**) c. 17.

<sup>(</sup>e) Section 5A was inserted by S.I. 2007/3101.

#### Amendment of section 29A

- **97.**—(1) Section 29A (appeals against decisions of the General Council)(a) is amended as follows.
  - (2) In subsection (2), after paragraph (b), insert—
    - "(c) a decision of the General Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (3) In subsection (3)(b), after "against" insert "or, in the case of an appeal from a decision falling within subsection (2)(c), direct that the alert be withdrawn or amended".

#### Amendment of section 43

- **98.**—(1) Section 43 (interpretation)(**b**) is amended as follows.
- (2) For the definition of "the General Systems Regulations", substitute—

""the General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

## PART 7

## SOCIAL WORKERS

#### CHAPTER 1

#### AMENDMENT OF THE CARE STANDARDS ACT 2000

## Introductory

99. The Care Standards Act 2000(c) is amended in accordance with this Chapter.

### **Amendment of section 55**

- **100.**—(1) Section 55 (interpretation)(**d**) is amended as follows.
- (2) After subsection (4), insert—
  - "(4A) "Social care manager" means a person who falls within the description in subsection (2)(c).".
- (3) For subsection (6), substitute—
  - "(6) "The General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059)."
- (4) In subsection (8)—
  - (a) in paragraph (b), after "work" insert ", or to engage in work as a social care manager in Wales,";
  - (b) in paragraph (c), after "work" insert ", or the right to engage in work as a social care manager in Wales,".

<sup>(</sup>a) Section 29A was inserted by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>b) Section 43 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>c) c. 14

<sup>(</sup>d) Section 55 was amended by section 95 of, and Schedule 5 to, the Health and Social Care Act 2008, and by S.I. 2007/3101 and 2011/1043. There are other amendments but these are not relevant to these Regulations.

#### **Amendment of section 56**

- **101.**—(1) Section 56 (the register)(**a**) is amended as follows.
- (2) In subsection (1)—
  - (a) in paragraph (b), omit the "and" at the end;
  - (b) in paragraph (c), at the end insert "; and";
  - (c) after paragraph (c), insert—
    - "(d) visiting social care managers from relevant European States.".
- (3) In subsection (2)—
  - (a) in paragraph (b), omit the "and" at the end;
  - (b) in paragraph (c), at the end insert "; and";
  - (c) after paragraph (c), insert—
    - "(d) for visiting social care managers from relevant European States.".
- (4) In subsection (2A)—
  - (a) in paragraph (c), after "European" insert "social worker";
  - (b) after paragraph (c), insert—
    - "(d) the part mentioned in subsection (2)(d) is the "visiting European social care manager part" of the register.".

#### **Amendment of section 58**

- **102.**—(1) Section 58 (grant or refusal of registration)(**b**) is amended as follows.
- (2) In subsection (2), after paragraph (a) insert—
  - "(aa) in the case of an applicant for registration as a social care manager—
    - (i) he satisfies the requirements of section 64A; or
    - (ii) he satisfies any requirements as to training which the Council may impose in relation to social care managers;".

#### **Amendment of section 58A**

- **103.**—(1) Section 58A (visiting social workers from relevant European States)(c) is amended as follows.
- (2) For "European part", in each place where the words occur, substitute "European social worker part".
  - (3) In subsection (2) for "8" substitute "12".
  - (4) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

## **Insertion of section 58B**

104. After section 58A, insert—

<sup>(</sup>a) Section 56 was amended by section 230 of, and Schedule 15 to, the Health and Social Care Act 2012 (c.7) and by S.I. 2007/3101.

<sup>(</sup>b) There are amendments to section 58, but these are not relevant to these Regulations.

<sup>(</sup>c) Section 58A was inserted by S.I. 2007/3101 and was amended by section 230 of, and Schedule 15 to, the Health and Social Care Act 2012.

## "Visiting social care managers from relevant European States

- **58B.**—(1) This section applies to an exempt person ("X") who is lawfully established as a social care manager in a relevant European State other than the United Kingdom.
- (2) Subsection (3) applies if X has the benefit of regulation 12 of the General Systems Regulations in connection with the provision by X of services as a social care manager in the United Kingdom on a temporary and occasional basis (X having complied with any requirements imposed under Part 2 of those Regulations in connection with the provision by X of services as a social care manager).
- (3) X is entitled to be registered in the visiting European social care manager part of the register, and the Welsh Council must give effect to the entitlement.
- (4) If X is entitled under subsection (3) to be registered in the visiting European social care manager part of the register but is not registered in that part, X is to be treated as having been registered in that part.
- (5) X's entitlement under subsection (3) ends if X ceases, whether as a result of the operation of regulation 24 of the General Systems Regulations or otherwise, to have the benefit of regulation 12 of those Regulations in connection with the provision by X of services as a social care manager in the United Kingdom on a temporary and occasional basis.
  - (6) If—
    - (a) X's entitlement under subsection (3) ceases by reason of the operation of subsection (5); and
- (b) X is registered in the visiting European social care manager part of the register, the Welsh Council may remove X from that part.
- (7) Subsections (1) to (6) are not to be taken to prejudice the application, in relation to persons registered in the visiting European social care manager part of the register, of rules under section 59.".

#### Amendment of section 60

- **105.**—(1) Section 60 (rules about registration)(**a**) is amended as follows.
- (2) In paragraph (c), after "section 58A(6)" insert ", section 58B(6)".

#### **Amendment of section 64**

- **106.**—(1) Section 64 (qualifications gained outside the Welsh Council's area)(**b**) is amended as follows.
  - (2) In the heading, at the end, insert "- social workers".

#### **Insertion of section 64A**

**107.** After section 64, insert—

## "Qualifications gained outside the Welsh Council's area - social care managers

**64A.** An applicant for registration as a social care manager in an added part of the register satisfies the requirements of this section if the applicant is an exempt person who by virtue of Part 3 of the General Systems Regulations is permitted to pursue the profession of social care manager in the United Kingdom (having, in particular, successfully completed any

<sup>(</sup>a) Section 60 was amended by section 230 of, and Schedule 15 to, the Health and Social Care Act 2012, and by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>b) The heading to section 64 was substituted by section 230 of, and Schedule 15 to, the Health and Social Care Act 2012. There are other amendments to section 64, but these are not relevant to these Regulations.

adaptation period, or passed any aptitude test, that the applicant may be required to undertake pursuant to that Part of those Regulations).".

#### Amendment of section 65

- **108.**—(1) Section 65 (post registration training)(a) is amended as follows.
- (2) In subsection (2A)—
  - (a) for "part of the register," substitute "social worker part of the register, or as a social care manager only in the visiting European social care manager part of the register,";
  - (b) omit ", respectively,".
- (3) In subsection (2B), after "worker", in both places where the word occurs, insert "or social care manager".
  - (4) In subsection (2C), after "worker" insert "or social care manager".
  - (5) In subsection (2D), after "worker" insert "or social care manager".

#### **Amendment of section 68**

- **109.**—(1) Section 68 (appeals to the Tribunal)(**b**) is amended as follows.
- (2) After subsection (1A), insert—
  - "(1B) An appeal shall lie to the Tribunal against a decision of the Welsh Council under Part 3 of the General Systems Regulations in respect of an aptitude test, or period of adaptation, in connection with a person becoming permitted, by virtue of that Part of those Regulations, to have access to, and to pursue, the profession of social care manager in the United Kingdom.
  - (1C) An appeal shall lie to the Tribunal against a decision of the Welsh Council under regulation 67 of the General Systems Regulations to send an alert about a person.".
- (3) In subsection (2), after "effect" insert "or, in the case of an appeal under subsection (1C), direct that the alert be withdrawn or amended".

#### Amendment of section 71

- **110.**—(1) Section 71(rules)(**c**) is amended as follows.
- (2) In subsection (3A), for "European part" substitute "European social worker part or visiting European social care manager part".

## CHAPTER 2

## AMENDMENT OF THE HEALTH AND PERSONAL SOCIAL SERVICES ACT (NORTHERN IRELAND) 2001

## Introductory

111. The Health and Personal Social Services Act (Northern Ireland)  $2001(\mathbf{d})$  is amended in accordance with this Chapter.

<sup>(</sup>a) Section 65 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>b) Section 68 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>c) Section 71(3A) was inserted by S.I. 2007/3101 and amended by section 230 of, and Schedule 15 to, the Health and Social Care Act 2012. There are other amendments to section 71, but these are not relevant to these Regulations.

<sup>(</sup>d) c. 3 (N.I.).

#### Amendment of section 2

- 112.—(1) Section 2 ("social care worker", etc.)(a) is amended as follows.
- (2) For subsection (5), substitute—
  - "(5) "The General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059)."

#### Amendment of section 5A

- **113.**—(1) Section 5A (visiting social workers from relevant European States)(**b**) is amended as follows
  - (2) In subsection (2), for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

#### Amendment of section 15

- 114.—(1) Section 15 (appeals to the Care Tribunal)(c) is amended as follows.
- (2) In subsection (2)(b), after "decision" insert "or, in the case of an appeal from a decision falling within subsection (3)(c), direct that the alert be withdrawn or amended".
  - (3) In subsection (3)—
    - (a) in paragraph (a), omit the "and" at the end;
    - (b) in paragraph (b), at the end, insert ", and";
    - (c) after paragraph (b), insert—
      - "(c) a decision under regulation 67 of the General Systems Regulations to send an alert about a person.".

## CHAPTER 3

## AMENDMENT OF THE REGULATION OF CARE (SCOTLAND) ACT 2001

#### Introductory

115. The Regulation of Care (Scotland) Act 2001(d) is amended in accordance with this Chapter.

### Amendment of section 46A

- **116.**—(1) Section 46A (visiting social workers from relevant European States)(**e**) is amended as follows.
  - (2) In subsection (2), for "8" substitute "12".
  - (3) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".
- (a) Section 2 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.
- (b) Section 5A was inserted by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.
- (c) Section 15 was substituted by section 5 of the Health and Personal Social Services (Amendment) Act (Northern Ireland) 2016 (c.23 (N.I.)).
- (d) 2001 asp 8.
- (e) Section 46A was inserted by S.I. 2007/3101.

#### Amendment of section 51

- 117.—(1) Section 51 (appeal against decision of Council)(a) is amended as follows.
- (2) In subsection (1)(a), omit the "or" at the end.
- (3) In subsection (1)(b), at the end, insert "or".
- (4) In subsection (1), after paragraph (b), insert—
  - "(c) has been given notice of a decision under regulation 67 of the General Systems Regulations to send an alert about the person,".
- (5) In subsection (2)(b), after "effect" insert "or, in the case of an appeal under subsection (1)(c), direct that the alert be withdrawn or amended".

#### Amendment of section 77

- **118.**—(1) Section 77 (interpretation)(**b**) is amended as follows.
- (2) For the definition of "the General Systems Regulations", substitute—

""the General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

#### **CHAPTER 4**

# AMENDMENT OF THE REGULATION AND INSPECTION OF SOCIAL CARE (WALES) ACT 2016

#### Introductory

**119.** The Regulation and Inspection of Social Care (Wales) Act 2016(c) (Deddf Rheoleiddio ac Arolygu Gofal Cymdeithasol (Cymru) 2016) is amended in accordance with this Chapter.

## Amendment of section 66 (English text)

- **120.**—(1) In the English language text, section 66(1) (interpretation of Parts 3 to 8) is amended as follows.
  - (2) In the appropriate places, insert—
    - "social care manager" ("rheolwr gofal cymdeithasol") has the meaning given by section 79(1)(b);";
    - ""visiting European social care manager part" ("rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad"), in relation to the register, is to be interpreted in accordance with section 80(3);";
    - ""visiting European social worker part" ("rhan gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad"), in relation to the register, is to be interpreted in accordance with section 80(3).".
  - (3) Omit the definition of "visiting European part".

# Amendment of section 66 (Welsh text)

- **121.**—(1) In the Welsh language text, section 66(1) (dehongli Rhannau 3 i 8) is amended as follows
  - (2) In the appropriate places, insert—

<sup>(</sup>a) Section 51 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>b) There are amendments but these are not relevant to these Regulations.

<sup>(</sup>c) 2016 anaw 2.

"mae i "rheolwr gofal cymdeithasol" ("social care manager") yr ystyr a roddir gan adran 79(1)(b).";

"mae "rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad" ("visiting European social care manager part"), mewn perthynas â'r gofrestr, i'w ddehongli yn unol ag adran 80(3);";

"mae "rhan gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad" ("visiting European social worker part"), mewn perthynas â'r gofrestr, i'w ddehongli yn unol ag adran 80(3);".

(3) Omit the definition of "rhan ymwelwyr Ewropeaidd".

## Amendment of section 74 (English text)

- **122.**—(1) In the English language text, section 74(3) (rules: fees) is amended as follows.
- (2) For "European part", substitute "European social worker part or visiting European social care manager part".

## **Amendment of section 74 (Welsh text)**

- **123.**—(1) In the Welsh language text, section 74(3) (rheolau: ffioedd) is amended as follows.
- (2) For "rhan ymwelwyr Ewropeaidd", substitute "rhan gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad neu'r rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad".

### Amendment of section 79 (English text)

- **124.**—(1) In the English language text, section 79(1)(b) (meaning of "social care worker" etc) is amended as follows.
  - (2) After "provided", insert "(referred to in those Parts as a "social care manager")".

## Amendment of section 79 (Welsh text)

- **125.**—(1) In the Welsh language text, section 79(1)(b) (ystyr "gweithiwr gofal cymdeithasol" etc.) is amended as follows.
- (2) After "ohono", insert "(y cyfeirir ato yn y Rhannau hynny fel "rheolwr gofal cymdeithasol")".

## Amendment of section 80 (English text)

- **126.**—(1) In the English language text, section 80 (the register) is amended as follows.
- (2) In subsection (1)—
  - (a) in paragraph (b), omit the "and" at the end;
  - (b) in paragraph (c), at the end insert ", and";
  - (c) after paragraph (c), insert—
    - "(d) visiting social care managers from relevant European States (see section 90A).".
- (3) In subsection (2), after paragraph (c) insert—
  - "(d) for visiting social care managers from relevant European States.".
- (4) In subsection (3)—
  - (a) in paragraph (c), after "European" insert "social worker";
  - (b) after paragraph (c), insert—
    - "(d) the part mentioned in subsection (2)(d) is the "visiting European social care manager part" of the register.".

### Amendment of section 80 (Welsh text)

- 127.—(1) In the Welsh language text, section 80 (y gofrestr) is amended as follows.
- (2) In subsection (1)—
  - (a) in paragraph (b), omit the "ac" at the end;
  - (b) in paragraph (c), at the end insert ", a";
  - (c) after paragraph (c), insert—
    - "(d) o reolwyr gofal cymdeithasol sydd ar ymweliad o Wladwriaethau Ewropeaidd perthnasol (gweler adran 90A).".
- (3) In subsection (2), after paragraph (c) insert—
  - "(d) ar gyfer rheolwyr gofal cymdeithasol sydd ar ymweliad o Wladwriaethau Ewropeaidd perthnasol.".
- (4) In subsection (3)—
  - (a) in paragraph (c), for "ymwelwyr Ewropeaidd" substitute "gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad";
  - (b) after paragraph (c), insert—
    - "(d) y rhan a grybwyllir yn is-adran (2)(d) yw'r "rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad.".

## Amendment of section 84 (English text)

- **128.**—(1) In the English language text, section 84 ("appropriately qualified") is amended as follows.
  - (2) In paragraph (a)(ii), after "Wales" insert "- social workers".
  - (3) After paragraph (a), insert—
    - "(aa) in the case of an application for registration as a social care manager, the applicant—
      - (i) has successfully completed a course approved by SCW under section 114 for persons wishing to become social care managers,
      - (ii) satisfies the requirements of section 85A (qualifications gained outside Wales social care managers), or
      - (iii) satisfies any requirements as to training which SCW may by rules impose in relation to social care managers;".

#### Amendment of section 84 (Welsh text)

- **129.**—(1) In the Welsh language text, section 84 ("wedi ei gymhwyso'n briodol") is amended as follows.
  - (2) In paragraph (a)(ii), after "Gymru" insert "– gweithwyr cymdeithasol".
  - (3) After paragraph (a), insert—
    - "(aa) os yw'r ymgeisydd, yn achos cais i gofrestru fel rheolwr gofal cymdeithasol—
      - (i) wedi cwblhau'n llwyddiannus gwrs a gymeradwywyd gan GCC o dan adran 114 ar gyfer personau sy'n dymuno dod yn rheolwyr gofal cymdeithasol,
      - (ii) yn bodloni gofynion adran 85A (cymwysterau a geir tu allan i Gymru rheolwyr gofal cymdeithasol), neu
      - (iii) yn bodloni unrhyw ofynion o ran hyfforddiant y caiff GCC drwy reolau eu gosod mewn perthynas â rheolwyr gofal cymdeithasol;".

### Amendment of section 85 (English text)

- **130.**—(1) In the English language text, section 85 (qualifications gained outside Wales) is amended as follows.
  - (2) In the heading, at the end, insert "- social workers".

#### Amendment of section 85 (Welsh text)

- **131.**—(1) In the Welsh language text, section 85 (cymwysterau a geir y tu allan i Gymru) is amended as follows.
  - (2) In the heading, at the end, insert "- gweithwyr cymdeithasol".

## Insertion of section 85A (English text)

132. In the English language text, after section 85, insert—

# "Qualifications gained outside Wales - social care managers

**85A.** An applicant for registration as a social care manager in an added part of the register satisfies the requirements of this section if the applicant is an exempt person who by virtue of Part 3 of the General Systems Regulations is permitted to pursue the profession of social care manager in the United Kingdom (having, in particular, successfully completed any adaptation period, or passed any aptitude test, that the applicant may be required to undertake pursuant to that Part of those Regulations).".

# Insertion of section 85A (Welsh text)

**133.** In the Welsh language text, after section 85, insert—

## "Cymwysterau a geir y tu allan i Gymru - rheolwyr gofal cymdeithasol

**85A.** Mae ymgeisydd ar gyfer cofrestru fel rheolwr gofal cymdeithasol mewn rhan ychwanegol o'r gofrestr yn bodloni gofynion yr adran hon os yw'r ymgeisydd yn berson esempt sydd, yn rhinwedd Rhan 3 o'r Rheoliadau Systemau Cyffredinol wedi ei ganiatáu i ddilyn proffesiwn rheolwr gofal cymdeithasol yn y Deyrnas Unedig (ar ôl, yn benodol, gwblhau unrhyw gyfnod addasu yn llwyddiannus, neu basio unrhyw brawf tueddfryd, y caiff fod yn ofynnol i'r ymgeisydd ei gwblhau yn unol â'r Rhan honno o'r Rheoliadau hynny)."

## Amendment of section 90 (English text)

- **134.**—(1) In the English language text, section 90 (visiting social workers from relevant European States) is amended as follows.
- (2) For "European part", in each place where the words occur, substitute "European social worker part".
  - (3) In subsection (2), for "8" substitute "12".
  - (4) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".
  - (5) In subsection (8)—
    - (a) in the definition of "exempt person"—
      - (i) in paragraph (b), after "Wales" insert ", or to engage in work as a social care manager in Wales,";

- (ii) in paragraph (c), after "Wales," insert "or as regards the right to engage in work as a social care manager in Wales,";
- (b) for the definition of "the General Systems Regulations" substitute—

""the General Systems Regulations" ("y Rheoliadau Systemau Cyffredinol") means the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059);".

## Amendment of section 90 (Welsh text)

- **135.**—(1) In the Welsh language text, section 90 (gweithwyr cymdeithasol sydd ar ymweliad o Wladwriaethau Ewropeaidd perthnasol) is amended as follows.
- (2) For "ymwelwyr Ewropeaidd", in each place where the words occur, substitute "gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad".
  - (3) In subsection (2), for "8" substitute "12".
  - (4) In subsection (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".
  - (5) In subsection (8)—
    - (a) in the definition of "person esempt"—
      - (i) in paragraph (b), after "yng Nghymru" insert ", neu ymgymryd â gwaith fel rheolwr gofal cymdeithasol yng Nghymru,";
      - (ii) in paragraph (c), after "yng Nghymru" insert ", neu o ran yr hawl i ymgymryd â gwaith fel rheolwr gofal cymdeithasol yng Nghymru";
    - (b) for the definition of "y Rheoliadau Systemau Cyffredinol" substitute—

"ystyr "y Rheoliadau Systemau Cyffredinol" ("the General Systems Regulations") yw Rheoliadau'r Undeb Ewropeaidd (Cydnabod Cymwysterau Proffesiynol) 2015 (O.S. 2015/2059).".

# Insertion of section 90A (English text)

136. In the English language text, after section 90, insert—

## "Visiting social care managers from relevant European States

- **90A.**—(1) This section applies to an exempt person ("X") who is lawfully established as a social care manager in a relevant European State other than the United Kingdom.
- (2) Subsection (3) applies if X has the benefit of regulation 12 of the General Systems Regulations in connection with the provision by X of services as a social care manager in the United Kingdom on a temporary and occasional basis (X having complied with any requirements imposed under Part 2 of those Regulations in connection with the provision by X of services as a social care manager).
- (3) X is entitled to be registered in the visiting European social care manager part of the register, and the registrar must give effect to the entitlement.
- (4) If X is entitled under subsection (3) to be registered in the visiting European social care manager part of the register but is not registered in that part, X is to be treated as having been registered in that part.
- (5) X's entitlement under subsection (3) ends if X ceases, whether as a result of the operation of regulation 24 of the General Systems Regulations or otherwise, to have the benefit of regulation 12 of those Regulations in connection with the provision by X of services as a social care manager in the United Kingdom on a temporary and occasional basis.

- (6) If X is registered in the visiting European social care manager part of the register, the registrar may remove X from that part if X's entitlement under subsection (3) ends by reason of the operation of subsection (5).
- (7) Subsections (1) to (6) do not prevent sections 92 to 94 or Part 6 (social care workers: fitness to practice) from applying to persons registered in the visiting European social care manager part of the register.".

### **Insertion of section 90A (Welsh text)**

**137.** In the Welsh language text, after section 90, insert—

# "Rheolwyr gofal cymdeithasol sydd ar ymweliad o Wladwriaethau Ewropeaidd perthnasol

- **90A**.—(1) Mae'r adran hon yn gymwys i berson esempt ("X") sydd wedi ei sefydlu'n gyfreithlon fel rheolwr gofal cymdeithasol mewn Gwladwriaeth Ewropeaidd berthnasol ac eithrio'r Deyrnas Unedig.
- (2) Mae is-adran (3) yn gymwys os oes gan X fudd rheoliad 12 o'r Rheoliadau Systemau Cyffredinol mewn cysylltiad â'r ddarpariaeth o wasanaethau fel rheolwr gofal cymdeithasol gan X yn y Deyrnas Unedig ar sail dros dro ac achlysurol (os yw X wedi cydymffurfio ag unrhyw ofynion a osodir o dan Ran 2 o'r Rheoliadau hynny mewn cysylltiad â'r ddarpariaeth o wasanaethau fel rheolwr gofal cymdeithasol gan X).
- (3) Mae hawlogaeth gan X i gael ei gofrestru yn y rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr, a rhaid i'r cofrestrydd roi effaith i'r hawlogaeth.
- (4) Os oes gan X hawlogaeth o dan is-adran (3) i gael ei gofrestru yn y rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr ond nad yw wedi ei gofrestru yn y rhan honno, mae X i'w drin fel pe bai wedi ei gofrestru yn y rhan honno.
- (5) Mae hawlogaeth X o dan is-adran (3) yn dod i ben os yw X yn peidio, pa un ai o ganlyniad i weithredu rheoliad 24 o'r Rheoliadau Systemau Cyffredinol neu fel arall, â chael budd rheoliad 12 o'r Rheoliadau hynny mewn cysylltiad â'r ddarpariaeth o wasanaethau fel rheolwr gofal cymdeithasol gan X yn y Deyrnas Unedig ar sail dros dro ac achlysurol.
- (6) Os yw X wedi ei gofrestru yn y rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr, caiff y cofrestrydd dynnu X oddi ar y rhan honno os daw hawlogaeth X o dan is-adran (3) i ben o ganlyniad i weithredu is-adran (5).
- (7) Nid yw is-adrannau (1) i (6) yn atal adrannau 92 i 94 neu Ran 6 (gweithwyr gofal cymdeithasol: addasrwydd i ymarfer) rhag bod yn gymwys i bersonau sydd wedi eu cofrestru yn y rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr.".

## Amendment of section 105 (English text)

- **138.**—(1) In the English language text, section 105 (other appeals: decisions made under the General Systems Regulations) is amended as follows.
  - (2) In subsection (1)(a)—
    - (a) for "9(2)", substitute "13(2)";
    - (b) after "United Kingdom" insert "or as a social care manager in the United Kingdom";
    - (c) omit the "or" at the end.
  - (3) In subsection (1)(b)—
    - (a) after "United Kingdom" insert "or the profession of social care manager in the United Kingdom";
    - (b) at the end, insert ", or".

- (4) In subsection (1), after paragraph (b), insert—
  - "(c) under regulation 67 of those Regulations to send an alert about a person.".
- (5) In subsection (5)(b), after "made" insert "or, in the case of an appeal from a decision falling within subsection (1)(c), direct that the alert be withdrawn or amended".

## Amendment of section 105 (Welsh text)

- **139.**—(1) In the Welsh language text, section 105 (apelau eraill: penderfyniadau a wneir o dan y Rheoliadau Systemau Cyffredinol) is amended as follows.
  - (2) In subsection (1)(a)—
    - (a) for "9(2)", substitute "13(2)";
    - (b) after "y Deyrnas Unedig" insert "neu fel rheolwr gofal cymdeithasol yn y Deyrnas Unedig";
    - (c) omit the "neu" at the end.
  - (3) In subsection (1)(b)—
    - (a) after "y Deyrnas Unedig" insert "neu broffesiwn rheolwr gofal cymdeithasol yn y Deyrnas Unedig";
    - (b) at the end, insert ", neu".
  - (4) In subsection (1), after paragraph (b), insert—
    - "(c) o dan reoliad 67 o'r Rheoliadau hynny i anfon rhybudd ynglŷn â pherson.".
- (5) In subsection (5)(b), after "erbyn" insert "neu, yn achos apêl yn erbyn penderfyniad sy'n dod o fewn is-adran (1)(c), cyfarwyddo bod y rhybudd yn cael ei dynnu'n ôl neu ei ddiwygio."

#### Amendment of section 113 (English text)

- **140.**—(1) In the English language text, section 113 (continuing professional development) is amended as follows.
- (2) In subsection (3), for "part of the register," substitute "social worker part of the register, or as a social care manager only in the visiting European social care manager part of the register,".
- (3) In subsection (4), after "worker", in both places where the word occurs, insert "or social care manager".
  - (4) In subsection (5), after "worker" insert "or social care manager".

## Amendment of section 113 (Welsh text)

- **141.**—(1) In the Welsh language text, section 113 (datblygiad proffesiynol parhaus) is amended as follows.
- (2) In subsection (3), for "ymwelwyr Ewropeaidd o'r gofrestr yn unig," substitute "gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr yn unig, neu fel rheolwr gofal cymdeithasol yn y rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad o'r gofrestr yn unig,".
  - (3) In subsection (4)—
    - (a) in paragraph (a), after "cymdeithasol" insert "neu reolwr gofal cymdeithasol";
    - (b) in paragraph (b)(i), after "cymdeithasol" insert "neu'n rheolwr gofal cymdeithasol".
  - (4) In subsection (5), after "cymdeithasol" insert "neu reolwr gofal cymdeithasol".

## Amendment of section 164 (English text)

**142.**—(1) In the English language text, section 164 (meaning of "registered person" in Part 6) is amended as follows.

(2) For "European part", substitute "European social worker part or visiting European social care manager part".

## Amendment of section 164 (Welsh text)

- **143.**—(1) In the Welsh language text, section 164 (ystyr "person cofrestredig" yn Rhan 6) is amended as follows.
- (2) For "rhan ymwelwyr Ewropeaidd", substitute "rhan gweithwyr cymdeithasol Ewropeaidd sydd ar ymweliad neu'r rhan rheolwyr gofal cymdeithasol Ewropeaidd sydd ar ymweliad".

# Amendment of Schedule 3 (English text)

- **144.**—(1) In the English language text, Schedule 3 (minor and consequential amendments) is amended as follows.
- (2) In paragraph 39 (amendment to section 130H of the Mental Health Act 1983), after "European" insert "social worker".
- (3) In paragraph 42(b) (amendments to section 55 of the Care Standards Act 2000), after "subsections" insert "(4A),".

## Amendment of Schedule 3 (Welsh text)

- **145.**—(1) In the Welsh language text, Schedule 3 (mân ddiwygiadau a diwygiadau canlyniadol) is amended as follows.
- (2) In paragraph 39 (diwygiad i adran 130H o Ddeddf Iechyd Meddwl 1983), after "European" insert "social worker".
- (3) In paragraph 42(b) (diwygiadau i adran 55 o Ddeddf Safonau Gofal 2000), after "isadrannau" insert "(4A),".

## PART 8

## OTHER HEALTH PROFESSIONS

## CHAPTER 1

AMENDMENT OF THE HEALTH AND SOCIAL WORK PROFESSIONS ORDER 2001

### Introductory

**146.** The Health and Social Work Professions Order 2001(a) is amended in accordance with this Chapter.

## **Amendment of article 12**

- **147.**—(1) Article 12 (approved qualifications)(**b**) is amended as follows.
- (2) After paragraph (1)(b), insert—
  - "(ba) he is an exempt person and has a right to practise in the United Kingdom by virtue of holding a European professional card in accordance with regulations 56 to 61 of the General Systems Regulations;".

<sup>(</sup>a) S.I. 2002/254, the title of which was substituted by section 213 of the Health and Social Care Act 2012.

<sup>(</sup>b) Article 12 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

#### Amendment of article 13A

- **148.**—(1) Article 13A (visiting health or social work professions from a relevant European State)(a) is amended as follows.
  - (2) For paragraph (2), substitute—
    - "(2) Paragraph (3) applies if—
      - (a) V has the benefit of regulation 12 of the General Systems Regulations in connection with the provision by V of relevant services in the United Kingdom on a temporary and occasional basis (V having complied with any requirements imposed under Part 2 of those Regulations in connection with the provision by V of relevant services); or
      - (b) V has a right to practise in the United Kingdom on a temporary and occasional basis by virtue of holding a European professional card in accordance with regulations 51 to 55 of those Regulations.".
  - (3) In paragraph (5)—
    - (a) for "17" substitute "24";
    - (b) for "8" substitute "12".

#### Amendment of article 38

- **149.**—(1) Article 38 (appeals)(**b**) is amended as follows.
- (2) In paragraph (1A), after sub-paragraph (b), insert—
  - "(c) a decision of the Council under regulation 67 of the General Systems Regulations to send an alert about a person;
  - (d) a decision of the Council to revoke, or not to issue, extend or vary a European professional card under Part 4 of the General Systems Regulations;
  - (e) a failure by the Council to make a decision in relation to a European professional card within the time limit under regulation 51(1) or 56(1) of the General Systems Regulations.".
- (3) In paragraph (3)(b), after "against" insert "or, in the case of an appeal from a decision falling within paragraph (1A)(c), direct that the alert be withdrawn or amended".
- (4) In paragraph (3)(c), after "against" insert ", or the failure to make a decision falling within paragraph (1A)(e),".

#### **Insertion of article 49**

**150.** After article 48 (supplementary and transitional provisions and extent), insert—

# "Review

- **49.** By 1st November 2021, and subsequently at intervals not exceeding 5 years from that date, in accordance with section 30 of the Small Business, Enterprise and Employment Act 2015, the Secretary of State must—
  - (a) carry out a review of the amendments made to this Order by the European Qualifications (Health and Social Care Professions) Regulations 2016;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.".

<sup>(</sup>a) Article 13A was inserted by S.I. 2007/3101.

<sup>(</sup>b) Article 38 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

#### Amendment of Schedule 3

- **151.**—(1) Schedule 3 (interpretation)(**a**) is amended as follows.
- (2) In paragraph 1—
  - (a) for the definition of "General Systems Regulations", substitute—
    - ""General Systems Regulations" means the European Union (Recognition of Professional Qualifications) Regulations 2015;";
  - (b) in the appropriate place, insert—
    - ""European professional card" has the meaning given in Directive 2005/36/EC of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications, as amended from time to time;".

#### **CHAPTER 2**

# AMENDMENT OF THE HEALTH PROFESSIONS COUNCIL (REGISTRATION AND FEES) RULES ORDER OF COUNCIL 2003

## Introductory

**152.** The Health and Care Professions Council (Registration and Fees) Rules 2003, which are set out in the Schedule to the Health Professions Council (Registration and Fees) Rules Order of Council 2003(**b**), are amended in accordance with this Chapter.

#### Amendment of rule 4

- **153.**—(1) Rule 4 (applications for registration)(**c**) is amended as follows.
- (2) In paragraph (4)(a)(ii), omit the "or" at the end.
- (3) After paragraph (4)(a)(ii), insert—
  - "(iia) where the applicant is relying on article 12(1)(ba) of the Order, evidence that the applicant has obtained a European professional card; or".

## PART 9

## **MISCELLANEOUS**

# Amendment of the European Union (Recognition of Professional Qualifications) 2015

- **154.**—(1) The European Union (Recognition of Professional Qualifications) Regulations 2015(**d**) are amended as follows.
- (2) In Schedule 3 (professions in respect of which the right of the applicant to choose between an adaptation period and an aptitude test is displaced), in Part 2 (professions under regulation 34(b)), omit the reference to "pharmacy technician".

#### General saving provision: Switzerland

- **155.**—(1) The amendments made by Parts 2 to 8 of these Regulations are of no effect in relation to any action taken in relation to—
  - (a) an individual—

<sup>(</sup>a) Schedule 3 was amended by S.I. 2007/3101. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>b) S.I. 2003/1572.

<sup>(</sup>c) Rule 4 was substituted by S.I. 2016/693. There are other amendments but these are not relevant to these Regulations.

<sup>(</sup>d) S.I. 2015/2059.

- (i) who obtained his or her professional qualifications in Switzerland; or
- (ii) who lawfully practised in Switzerland,
- who wishes to access and pursue a regulated profession in the United Kingdom in reliance on those professional qualifications or that practice; or
- (b) matters affecting Switzerland, insofar as such action relates to Switzerland.
- (2) In this regulation—
  - (a) "professional qualifications" means the formal qualifications necessary to practice a profession in Switzerland that is equivalent to a regulated profession;
  - (b) "regulated profession" means a profession regulated by or under an enactment amended in Parts 2 to 8 of these Regulations.

Signed by authority of the Secretary of State for Health.

Philip Dunne Minister of State, Department of Health

25th October 2016

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations, which are made under powers contained in the European Communities Act 1972, implement, in part, amendments to Directive 2005/36/EC ("the Directive") made by Directive 2013/55/EU, which concerns the recognition of professional qualifications. The essential aim of the Directive is to facilitate the free movement of persons between Member States of the European Union, by setting out principles and procedures which Member States are to apply in determining the rights of migrants to pursue professions which require professional qualifications. Accordingly, the Regulations make amendments to a number of Acts and statutory instruments in order to reflect the changes made to the Directive.

The Regulations implement most of the changes made to the Directive in relation to a first group of health professions (the "sectoral professions"), namely, doctors (including specialists and general practitioners), pharmacists, dentists (including specialist dentists), nurses responsible for general care and midwives.

The Regulations implement certain provisions of the Directive in relation to a second group of health and social care professions (the "general systems professions"), namely, chiropractors, opticians, osteopaths, pharmacy technicians, social workers, social care managers, professions complementary to dentistry, certain specialist nurses and those professions regulated by the Health and Care Professions Council. These professions are not subject to the system of automatic mutual recognition of qualifications which applies in relation to the sectoral professions.

Those changes to the Directive relating to health and social care professions which are not implemented by these Regulations are implemented by the European Union (Recognition of Professional Qualifications) Regulations 2015 (S.I. 2015/2059) ("the General Systems Regulations").

The amendments made by these Regulations apply in relation to the Member States of the European Union and also in relation to the other EEA States, Iceland, Liechtenstein and Norway. The do not apply in relation to Switzerland (see regulation 155).

The main changes to existing legislation made by the Regulations may be summarised as follows.

Updating cross-references to the General Systems Regulations

These Regulations make a number of consequential amendments to update references in the legislation to reflect the General Systems Regulations and the revocation of the European Communities (Recognition of Professional Qualifications) Regulations 2007 (S.I. 2007/2781) by

those Regulations. For an example, see regulation 6 (which amends the cross-references to the General Systems Regulations in section 14A of the Medical Act 1983).

## European professional card

Articles 4a to 4e of the Directive are new provisions which, together with Commission Implementing Regulation 2015/983/EU ("the Implementing Act"), establish a new (and principally electronic) system for the recognition of professional qualifications in certain cases: the European professional card ("EPC"). The sectoral professionals benefitting from the EPC are pharmacists and nurses responsible for general care. These Regulations implement the EPC system in relation to pharmacists and nurses responsible for general care (in particular, see regulations 25, 42 and 69). In addition, physiotherapists benefit from the EPC system under Part 4 of the General Systems Regulations. See Annex I to the Implementing Act for the professions which are currently eligible for the EPC.

Declaration and evidence in relation to first provision of services, etc.

Article 7(2) of the Directive has been amended so that additional documentation or evidence must be submitted by visiting practitioners from relevant European States who are seeking permission to practise in the sectoral professions on a temporary and occasional basis for the first time or if there is a material change in their circumstances. That documentation or evidence consists of confirmation of the absence of temporary or final suspensions from practising and the absence of criminal convictions, and a declaration about the applicant's knowledge of English for the purpose of practising: see regulations 10, 24, 41, 53 and 68.

## Professional traineeships

Article 55a of the Directive (also see the amendments to article 2(1)) is a new provision setting out requirements as to the recognition of professional traineeships carried out overseas. The affected sectoral professions are doctors and pharmacists. In particular, see regulations 4, 5, 21 and 38 for these requirements. Regulations 9, 18 and 30 amend the relevant sectoral professions legislation by inserting definitions of "professional traineeship".

## Competent authority functions

Article 56(3) of the Directive requires relevant European States to designate competent authorities which will deal with applications and the provision of certificates etc., under the Directive. Regulations 11, 23, 25, 43, 54, 60 and 70 insert and update the functions of the relevant UK competent authorities for the sectoral professions.

## **Appeals**

The Regulations make changes regarding rights of appeal in relation to certain EPC decisions, and decisions to send alerts about practitioners, by the relevant UK competent authority: for example, see regulations 34 to 36 (which amend articles 39 to 41, respectively, of the Pharmacy Order 2010). See regulation 67 of the General Systems Regulations for details of the alert mechanism itself (which applies also in relation to the sectoral profession), and articles 23 to 28 of the Implementing Act.

An impact assessment of the effect that these Regulations will have on the cost of business, the voluntary sector and the public sector is available from the Department of Health on the gov.uk website (www.gov.uk). An Explanatory Memorandum and a transposition note are available with these Regulations on the www.legislation.gov.uk website.

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