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STATUTORY INSTRUMENTS

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**2016 No. 1030**

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

PART 3

PHARMACISTS AND PHARMACY TECHNICIANS

CHAPTER 3

AMENDMENT OF THE PHARMACY ORDER 2010

**Introductory**

29. The Pharmacy Order 2010(1) is amended in accordance with this Chapter.

**Amendment of article 3**

30.—(1) Article 3(1) (interpretation)(2) 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

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(1) [S.I. 2010/231](#).

(2) Regulation 3 was amended by [S.I. 2015/806](#). There are other amendments which are not relevant to these Regulations.

- (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 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)(3) 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—

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(3) Article 39 was amended by [S.I. 2014/1887](#) and [2015/806](#).

“(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)(4) 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”.

#### **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—

“SCHEDULE 2A

Article 33A

[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 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 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)(5) is amended as follows.

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

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“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.

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(5) Schedule 3 was amended by [S.I. 2015/806](#).

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.
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 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.”
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(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.
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Article 50(3b)	Ensuring that the exchange of information under article 50 of the Directive with other competent authorities takes place through the IMI.”
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(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—
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(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 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 <a href="#">Directive 95/46/EC</a> and <a href="#">Directive 2002/58/EC</a> .
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.”

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