
STATUTORY INSTRUMENTS

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

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.”.

Changes to legislation:

There are currently no known outstanding effects for the The European Qualifications (Health and Social Care Professions) Regulations 2016, Section 42.