STATUTORY INSTRUMENTS

# 2016 No. 1030

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

## PART 3

PHARMACISTS AND PHARMACY TECHNICIANS

CHAPTER 1

AMENDMENT OF THE PHARMACY (NORTHERN IRELAND) ORDER 1976

### Introductory

**17.** The Pharmacy (Northern Ireland) Order 1976 [M1] is amended in accordance with this Chapter.

**Marginal Citations**

**M1** S.I. 1976/1213 (N.I. 22).

### Amendment of article 2

**18.**—(1) Article 2(2) (interpretation) [M2] 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);"

[M3]

.

(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 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.".

**Marginal Citations**

**M2** 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.

**M3** The definition of "General Systems Regulations" was inserted by S.R. (N.I.) 2008 No. 192.

### Amendment of article 8

**19.**—(1) Article 8 (qualifications for registration) [M4] 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) ".

**Marginal Citations**

**M4** Article 8(2)(c) was substituted by S.R. (N.I.) 2008 No. 192.

### Amendment of article 8A

**20.** In article 8A (registration by virtue of appropriate European diploma) [M5], in paragraph (2), for "Subject to paragraph (8)" substitute " Subject to paragraph (7) ".

**Marginal Citations**

**M5** Article 8A was inserted by S.R. (N.I.) 1987 No. 457 and amended by 1996 No. 393 and 2008 No. 192.

### Insertion of articles 8C and 8D

**21.** After article 8B (visiting pharmaceutical chemist from a relevant European State) [M6], 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 (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).".

**Marginal Citations**

**M6** Article 8B was inserted by S.R. (N.I.) 2008 No. 192.

**Insertion of articles 11ZZA and 11ZZB**

**22.** After article 11 (evidence of qualification to be registered), insert [M7]—

"**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.

(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.”.

**Marginal Citations**

**M7** 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.

**Insertion of article 22A**

**23.** In Part 5 (miscellaneous), before article 23 (dispensing, etc., in public institutions) [M8], 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.".

**Marginal Citations**

**M8** Article 22 was originally in Part 4; articles 21 and 22 were revoked by S.R. (N.I.) 2012 No. 308.

### Amendment of Schedule 2B

**24.**—(1) Schedule 2B (visiting pharmaceutical chemist from a relevant European State) [M9] 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) ";

(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 ".

**Marginal Citations**

**M9** Schedule 2B was inserted by S.R. (N.I.) 2008 No. 192.

### Insertion of Schedules 2C and 2D

**25.** After Schedule 2B insert—

"SCHEDULE 2C Article 8D

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) P asks 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.<br>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. |

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| 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—<br><br>(a) the legality of a person's establishment as a pharmacist in Northern Ireland;<br><br>(b) the good conduct of such a person;<br><br>(c) the absence of any disciplinary or criminal sanctions of a professional nature against such a person.<br><br>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. |
| Article 23(1) | Issuing certificates of effective and lawful practice in Northern Ireland to pharmacists. |
| Article 23(6) | Issuing certificates stating that NI pharmacy qualifications, which do 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—<br>(a) that is in accordance with article 44 of the Directive; or<br>(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. |
| Article 50(1) and paragraph 1(b) of Annex VII | Providing information to other competent authorities concerning the training in Northern Ireland of a pharmacist to whom Chapter 1 of Part 3 of the General Systems Regulations applies. |
| Article 50(1) and paragraph 1(d) of Annex VII | Issuing, in respect of practice as a pharmacist, the certificates of current 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-paragraph. |
| Article 50(1) and paragraph 2 of Annex VII | Issuing certificates stating that evidence of NI pharmacy qualifications is that covered by the Directive. |
| Article 50(2) | In cases of justified doubts—<br><br>(a) requiring confirmation of the authenticity of non-UK pharmacy qualifications;<br><br>(b) requiring confirmation that holders of non-UK pharmacy qualifications satisfy the minimum training conditions set out in article 44 of the Directive |

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| | 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. |
| 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 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 pharmacist are compliant with article 53 of the Directive. |
| Article 55a | When considering an application for registration as a pharmacist, 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. |
| Article 56(1) | Ensuring the confidentiality of information exchanged with other 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 |

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| | carried out in accordance with Directive 95/46/EC and Directive 2002/58/EC and through the IMI. |
| 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 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. |
| 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 beginning with and including 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—<br>(a) a prohibition or a restriction referred to in article 56a(1) of the Directive has expired;<br>(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, 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—<br>(a) is the subject of an alert sent under article 56a(1) or (3) of the Directive;<br>(b) has the right to appeal the decision or to apply for rectification of the decision;<br>(c) has the right to access remedies in respect of any damage caused by false alerts sent to other competent authorities.<br><br>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—<br>(a) the date of adoption of the revoking decision; or<br>(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.” |

**Changes to legislation:**
There are currently no known outstanding effects for the The European Qualifications (Health and Social Care Professions) Regulations 2016, CHAPTER 1.