

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2018 No. 0000

**EXITING THE EUROPEAN UNION
HEALTH CARE AND
ASSOCIATED PROFESSIONS
PROFESSIONAL QUALIFICATIONS**

The European Qualifications (Pharmacists) (Amendment
etc.) (EU Exit) Regulations (Northern Ireland) 2018

Made - - - - *******

Laid before Parliament *******

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(1).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

Citation and commencement

1.—(1) These Regulations may be cited as the European Qualifications (Pharmacists) (Amendment etc.) (EU Exit) Regulations (Northern Ireland) 2018.

(2) These Regulations come into force on exit day.

Pharmacists

2. The Schedule contains—

- (a) amendments relating to pharmacists in Northern Ireland;
- (b) transitional and savings provision relating to those amendments.

Review of continued recognition of certain European qualifications

3.—(1) The Secretary of State must, after the end of the period of two years beginning with the day on which these Regulations come into force—

- (a) carry out a review of the operation of the provision contained in Article 8(2)(c), (2B) and (2C) of the Pharmacy (Northern Ireland) Order 1976 (which concerns the recognition to be given to certain European qualifications after exit day) as substituted and inserted by these Regulations;
- (b) set out the conclusions of the review in a report;
- (c) publish the report.

(2) The report must be published within the period of six months beginning with the day after the end of the period referred to in paragraph (1).

Signed by the authority of the Secretary of State for Health and Social Care.

Address
Date

Name
Minister of State,
Department of Health and Social Care

SCHEDULE

Regulation 2

Amendments relating to pharmacists in Northern Ireland

PART 1

Amendment of the 1976 Order

Interpretation

1.—(1) In this Schedule, the “1976 Order” means the Pharmacy (Northern Ireland) Order 1976(2).

(2) The Interpretation Act (Northern Ireland) 1954(3) applies to Part 3 of this Schedule as it applies to a Part of a Schedule to an Act of the Assembly.

Pharmacy (Northern Ireland) Order 1976

2. The 1976 Order is amended as follows.

3. In Article 2(2) (interpretation)(4)—

- (a) omit the definitions of “competent authorities”, “[Directive 2002/58/EC](#)”, “the Directive”, “European professional card”, “exempt person”, “General Systems Regulations”; “IMI”, “IMI file”, “national”, “reference date”, “relevant European State” and “third country”;
- (b) in the definition of “registered”, omit “visiting pharmaceutical chemist from a relevant European State”;
- (c) in the definition of “registered person”, omit “, visiting pharmaceutical chemist from a relevant European State”.

4. In Article 4A (continuing professional development)(5), omit paragraphs (7)(c), (10)(b) and (14).

5. In Article 5 (regulations made by the Council: general)(6), omit paragraph (1A).

6. In Article 6 (the registers)(7)—

- (a) in paragraph (1), omit “, and in relation to the register mentioned in sub-paragraph (d) there shall be kept,”;
- (b) after paragraph (1)(b), insert “and”;
- (c) omit paragraph (1)(d) and the “and” before it.

7. In Article 8 (qualifications for registration)(8)—

- (a) for paragraph (2)(c), substitute—
“(c) every person who holds a relevant European qualification.”;
- (b) after paragraph (2A), insert—

(2) [S.R. 1976/1213](#). (N.I. 22)

(3) [1954 c.33](#).

(4) Relevant amending instruments are [S.R. 1987/457](#) and [2008/192](#) and [S.I. 2016/1030](#).

(5) Article 4A was inserted by [S.R. 2012/308](#).

(6) Paragraph (1A) was inserted by [S.R. 2008/192](#).

(7) Paragraph (1) was substituted by [S.R. 2008/192](#).

(8) Paragraph (2)(c) was substituted by [S.R. 2008/192](#) and paragraph (2A) was inserted by [S.I. 2015/806](#). Relevant amending instrument is [S.I. 2016/1030](#).

“(2B) In paragraph (2)(c), “a relevant European qualification” means a qualification that falls within Article 8A (relevant European qualifications) and has not been designated by the registrar for the purposes of this paragraph.

(2C) The registrar—

- (a) may designate a qualification for the purposes of paragraph (2B) only with the approval of the Department;
- (b) must maintain and publish a list of the qualifications that are so designated.”.

8. For Article 8A (registration by virtue of appropriate European diploma)(9), including the heading, substitute—

“Relevant European qualifications

8A.—(1) Subject to the following provisions of this Article, a qualification falls within this Article if it was awarded in a relevant European State and is listed in Annex V, point 5.6.2 of the Directive.

(2) A qualification falls within this Article only if it is accompanied, where applicable, by the certificate listed in relation to the qualification in the column entitled “Certificate accompanying the diploma” in Annex V, point 5.6.2 of the Directive.

(3) A qualification does not fall within this Article if it was awarded before the reference date, or is evidence of training begun before that date.

(4) In this Article—

- (a) “the Directive” means [Directive 2005/36/EC](#) of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications (OJ No L255, 30.09.2005, p22); and references in this Article to the Directive or to a provision of the Directive is a reference to the Directive, or to that provision, as it had effect immediately before exit day;
- (b) “reference date” means the date listed in relation to the State in which the qualification was awarded in the column entitled “Reference date” in Annex V, point 5.6.2 of the Directive;
- (c) “relevant European State” means an EEA State or Switzerland.

Relevant European qualification: indication in the register

8ZA. Where a person is registered by virtue of Article 8(2)(c), an indication that the person has been registered in respect of a relevant European qualification shall be entered in the register against the person’s name.”.

9. In Article 8AA (supplementary provisions as to the necessary knowledge of English)(10), omit paragraphs (5) and (7).

10. Omit Article 8B (visiting pharmaceutical chemist from a relevant European State)(11).

11. Omit Article 8C (professional traineeships carried out in other relevant European States, etc.)(12).

12. Omit Article 8D (European professional card)(13).

(9) Article 8A was inserted by [S.R. 1987/457](#).

(10) Article 8AA was inserted by [S.I. 2015/806](#).

(11) Article 8B was inserted by [S.R. 2008/192](#).

(12) Article 8C was inserted by [S.R. 2016/130](#).

(13) Article 8D was inserted by [S.R. 2016/130](#).

13. In Article 9(2) (the registrar)(14), for “and, (c) and (d)” substitute “and (c)”.
14. In Article 11 (evidence of qualification to be registered)(15)—
 - (a) after paragraph (1) insert—

“(1ZA) Article 8A does not restrict what may otherwise be done by the registrar under paragraph (1) in order to be satisfied as referred to in that paragraph.”;
 - (b) omit paragraph (1A).
15. Omit Article 11ZZA (appeals: decisions in relation to alerts and European professional cards)(16).
16. Omit Article 11ZZB (appeals to the Council under Article 11ZZA)(17).
17. Omit Article 11ZA (recognition of qualification of exempt persons)(18).
18. In Article 11A (indemnity arrangements)(19), omit paragraph (12).
19. In Article 14(2A) (issue of certificates of registration and penalties for failure to surrender, or abuse of, certificates)(20), for “8A(1)” substitute “8ZA”.
20. Omit Article 22A (the Directive: functions of competent authority, etc.)(21).
21. Omit Schedule 2A (table in respect of training in the former Czechoslovakia, the former Soviet Union or the former Yugoslavia)(22).
22. Omit Schedule 2B (visiting pharmaceutical chemist from a relevant European State)(23).
23. Omit Schedule 2C (Directive 2005/36/EC: European professional card)(24).
24. Omit Schedule 2D (the Directive: functions of the Society under Article 22A)(25).

PART 2

Amendment of other legislation

Amendments

25. In Article 63AA(3)(c) (persons providing pharmaceutical services) of Health and Personal Social Services (Northern Ireland) Order 1972(26), for “(qualification by European diploma)” substitute “(relevant European qualification)”.
26. In regulation 6(12) (pharmaceutical list) of the Pharmaceutical Services Regulations (Northern Ireland) 1997(27), for “(qualification by European diploma)” substitute “(relevant European qualification)”.

(14) Relevant amending instrument is [S.R. 2008/192](#).

(15) Paragraph (1A) was inserted by [S.R. 2008/192](#).

(16) Article 11ZZA was inserted by [S.I. 2016/1030](#).

(17) Article 11ZZB was inserted by [S.I. 2016/1030](#).

(18) Article 11ZA was inserted by [S.I. 2015/806](#).

(19) Article 11A was inserted by [S.R. 2013/258](#).

(20) Paragraph (2A) was inserted by [S.R. 1987/457](#). Relevant amending instrument is [S.R. 2008/192](#).

(21) Article 22A was inserted by [S.I. 2016/1030](#).

(22) Schedule 2A was substituted by [S.R. 2008/192](#).

(23) Schedule 2B was substituted by [S.R. 2008/192](#).

(24) Schedule 2C was inserted by [S.I. 2016/1030](#).

(25) Schedule 2D was inserted by [S.I. 2016/1030](#).

(26) [S.I. 1972/1265 \(N.I. 14\)](#). Article 63AA was inserted by [2008 \(N.I. 2\)](#).

(27) [S.R. 1997/381](#). Relevant amending instrument is [S.R. 2001/222](#).

27.—(1) The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations 2012(**28**) are amended as follows.

(2) In regulation 2 (failure to comply with the CPD framework), omit paragraph (7)(b)(ii) and the “or” before it.

(3) In regulation 3 (steps which the registrar may take), omit paragraph (3).

(4) In regulation 4 (remedial measures), omit paragraph (1)(f)(ii) and the “or” before it.

Revocations

28. The following instruments are revoked—

(a) the European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008(**29**),

(b) the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008(**30**).

PART 3

Transitional and saving provision relating to the amendments in Parts 1 and 2

Pending applications

29. Where an application for registration, or retention, in a part of the register kept under the 1976 Order is received before exit day, any provision made by or under that Order (except for provision contained in Schedule 2C to the Order) continues to apply in relation to the application (including any appeal arising from it) without the amendments made by Part 1 or 2 of this Schedule.

Visiting practitioners from relevant European States – saving of old law for up to one year

30.—(1) Where, immediately before exit day—

(a) a visiting practitioner was entitled under paragraph 4 or 7 of Schedule 2B to the 1976 Order to provide occasional pharmacy services, or

(b) the registrar was in receipt of the required documents (within the meaning of paragraph 5 of that Schedule) from a visiting practitioner seeking to acquire that entitlement,

any provision made by an Act or instrument amended by Part 1 or 2 of this Schedule continues to apply in relation to the practitioner without the amendments that Part 1 or 2 of this Schedule makes to the provisions relating to visiting practitioners from relevant European States.

(2) But a visiting practitioner’s entitlement does not continue (or further continue) under paragraph 7 of Schedule 2B to the 1976 Order on or after exit day (and, accordingly, the entitlement lapses at the end of the period mentioned in paragraph 8(1) or (2) of that Schedule).

(3) The reference in sub-paragraph (1) to “the provisions relating to visiting practitioners from relevant European States” is to the provisions listed in the following table.

<i>Instrument</i>	<i>Provisions relating to visiting practitioners</i>
The 1976 Order	In Article 2(2), the definitions of “competent authorities”, “exempt person”, “General Systems

(28) [S.R. 2012/312](#).

(29) [S.R. 2008/192](#).

(30) [S.R. 2008/193](#).

<i>Instrument</i>	<i>Provisions relating to visiting practitioners</i>
	Regulations”, “national”, “registered”, “relevant European State” and “registered person”
	Article 4A(7)(c), (10)(b) and (14)
	Article 5(1A)
	Article 6(1)
	Article 8B
	Article 9(2)
	Article 11A(12)
	Schedule 2B
The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012	Regulation 2(7)(b)(ii)
	Regulation 3(3)
	Regulation 4(1)(f)(ii)

European professional card

31.—(1) Sub-paragraph (2) applies where, immediately before exit day—

- (a) a person held a valid European professional card for establishment as a pharmaceutical chemist in Northern Ireland, or
- (b) the Society was in receipt of a person’s application for such a card, the application having been transmitted to it under Article 4d(1) of the Directive.

(2) For the purposes of registration in the register kept under the 1976 Order, the person is not required to resubmit any document or evidence held by the Society which is derived from the person’s IMI file and which does not appear to the Society to have become invalid.

(3) In this paragraph—

- (a) “the Directive” means [Directive 2005/36/EC](#) of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications (OJ No L255, 30.09.2005, p 22), as it had effect immediately before exit day;
- (b) “IMI file” has the meaning given by Article 2 of the 1976 Order as it had effect immediately before exit day.

32.—(1) Where immediately before exit day, a person was entitled as mentioned in paragraph 15(2) of Schedule 2C to the 1976 Order, any provision made by or under that Order continues to apply in relation to the person without the amendments made by Part 1 or 2 of this Schedule to the provisions relating to the provision of occasional pharmacy services by holders of a European professional card.

(2) For the purposes of paragraph 15(4)(a) of Schedule 2C to the 1976 Order as it continues to apply by virtue of sub-paragraph (1), a European professional card that was transmitted as mentioned in paragraph 15(1)(a) of that Schedule is to be treated as becoming invalid on the expiry of the period of 18 months beginning with the day on which it was transmitted.

(3) The reference in sub-paragraph (1) to “the provisions relating to the provision of occasional pharmacy services by holders of a European professional card” is to the provisions listed in the following table.

<i>Instrument</i>	<i>Provisions relating to visiting practitioners holding a European professional card</i>
The 1976 Order	<p>In Article 2(2), the definitions of “competent authorities”, “European professional card”, “General Systems Regulations”, “IMI”, “IMI file”, “registered”, “relevant European State” and “registered person”</p> <p>Article 4A(7)(c), (10)(b) and (14)</p> <p>Article 5(1A)</p> <p>Article 6(1)</p> <p>Article 8B</p> <p>Article 8D</p> <p>Article 9(2)</p> <p>In Schedule 2C, paragraphs 2 (except the definitions of “EPC holder” and “missing document”), 15 and 16</p>
The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012	<p>Regulation 2(7)(b)(ii)</p> <p>Regulation 3(3)</p> <p>Regulation 4(1)(f)(ii)</p>

33.—(1) A decision within Article 11ZZA(b) of the 1976 Order taken before exit day, or a failure within Article 11ZZA(c) of that Order arising before exit day, continues to be appealable for the purposes of Article 11ZZB of that Order (subject to the provisions of the Order) despite the revocation of Article 11ZZA(b) and 11ZZA(c).

(2) In disposing of such an appeal, the powers of the Council are, instead of those set out in Article 11ZZB(4), to—

- (a) dismiss the appeal;
- (b) allow the appeal and direct the Society to take such steps as the Council thinks fit to draw the findings of the Council to the European Commission; or
- (c) direct that the person in respect of whom the decision was taken (or the failure arose) is to be treated, for the purposes of paragraph 31(1)(a), as a person who held a valid European professional card for establishment as a pharmaceutical chemist in Northern Ireland immediately before exit day.

IMI Alerts

34.—(1) Where an alert has been sent by the Society before exit day under regulation 67 of the European Union (Recognition of Professional Qualifications) Regulations 2015(a) (as they had effect before exit day), the decision to send the alert continues to be appealable for the purposes of Article 11ZZA of the 1976 Order (subject to the provisions of that Order) despite the revocation of Article 11ZZB.

(2) In disposing of such an appeal, the powers of the Council are, instead of those set out in Article 11ZZB(4), to—

- (a) dismiss the appeal, or

- (b) allow the appeal and direct the Society to take such steps as the Council thinks fit to draw the findings of the Council to the attention of the European Commission.

Interpretation of Saved Provisions

35. Where a provision continues to apply by virtue of this Part, it is to be read as if—

- (a) in Article 2(2) of the 1976 Order—

- (i) there were substituted for the definition of “the Directive”—

““the Directive” means [Directive 2005/36/EC](#) of the European Parliament and of the Council of 7th September 2005 on the recognition of professional qualifications (OJ L255, 30.09.2005, p 22), and any reference in this Order to the Directive or to any provision of the Directive is a reference to the Directive, or to that provision, as it had effect immediately before exit day;”;

- (ii) there were inserted at the appropriate place—

““enforceable EU right” means a right recognised and available in domestic law, immediately before exit day, by virtue of section 2(1) of the European Communities Act 1972;”;

- (iii) in the definition of “exempt person”, for paragraphs (a) to (c) there were substituted—

“(a) a person who, immediately before exit day, was a national of a relevant European State,

(b) a person who, immediately before exit day, was a national of the United Kingdom and, at that time, was seeking access to, or pursuing, the profession of pharmacy by virtue of an enforceable EU right, or

(c) a person who, immediately before exit day, was not a national of a relevant European State, but at that time was, by virtue of an enforceable EU right, entitled to be treated, for the purposes of access to and pursuit of the profession of pharmacy, no less favourably than a national of relevant European State;”;

- (iv) in the definition of “General Systems Regulations”, after “[S.I. 2015/2059](#)” there were inserted—

“—

(a) in relation to anything done before exit day, as they had effect at that time;

(b) otherwise, as (and only to the extent that) they have effect on and after exit day, in relation to an entitlement which arose before exit day or arises after as a result of something done before exit day;”;

- (b) in any reference to “a relevant European State other than the United Kingdom”, the words “other than the United Kingdom” were omitted.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of domestic legislation to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

These Regulations amend legislation concerned with the regulation of pharmacy professionals in Northern Ireland.

They amend the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265), the Pharmacy (Northern Ireland) Order 1976 (S.R. 1976/1213 (N.I. 22)), the Pharmaceutical Services Regulations (Northern Ireland) 1997 (S.R. 1997/381) and the Council of Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations 2012/312. They revoke the European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192) and the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 (S.R. 2008/193).

Regulation 3 requires the Secretary of State to perform a review of provisions dealing with recognition of European Union qualifications within the Regulations. The Secretary of State is also required to produce and publish the conclusions of the review.

Part 1 of the Schedule removes rights and obligations under Directive 2005/36/EC (“the Directive”). The Directive is concerned with the recognition of professional qualifications across the European Union, including the recognition of pharmacists.

Part 1 of the Schedule removes provisions currently dealing with registration of and registers for “visiting” practitioners from relevant European States. “Visiting” practitioners provide services on a temporary and occasional basis, rather than becoming established in their profession in the UK. Part 3 of the Schedule saves certain provisions relating to “visiting” practitioners so that those who are entitled and have provided all documentation required to acquire that entitlement, before exit day, or have a pending application as at exit day, are dealt with under the current legislation. The savings provisions do not permit renewals of registrations under the “visiting” system.

Part 1 of the Schedule omits the definitions for and removes references to “exempt person” and “General Systems Regulations”. An “exempt person” is a person with certain rights under European Union legislation. These rights will no longer be available in the UK after exit day. The “General Systems Regulations” currently provide a domestic legislative basis for recognition of certain European qualifications. They also provide for regulators to require individuals to undertake compensatory measures and/or adaption periods where European qualifications fall short of the standards required by the Pharmaceutical Society of Northern Ireland (“the PSNI”). After exit day PSNI will not refer to the amended “General Systems Regulations” for new registrations.

Part 1 of the Schedule provides that qualifications and diplomas issued by relevant European States and currently recognised as giving automatic recognition in other relevant European States, will be qualifications enabling registration as a pharmaceutical chemist, unless a particular qualification or diploma has been designated by the registrar. Amendments provide that such designation will be subject to approval by the Department.

Part 1 of the Schedule removes or amends provisions giving those with rights under European legislation special treatment in relation to fees for registration, indemnity provisions and language testing requirements.

Part 1 of the Schedule omits references to “[Directive 2002/58/EC](#)” [Directive 2002/58/EC](#) is concerned with privacy and electronic communications. In the same part of these Schedules references to “the Directive” have been omitted or amended where required. The UK will no longer be subject to obligations imposed by Directives after exit day.

Part 1 of the Schedule also removes or amends (where required) references to “competent authority”. A competent authority is an authority or body within a relevant European State that has obligations or rights under the Directive to receive or issue evidence and information connected to qualifications, and to receive applications and take decisions under the Directive. In NI the Pharmaceutical Society for Northern Ireland holds this status. Competent authorities in the UK will no longer have rights and obligations under “the Directive” after exit day.

Part 1 of the Schedule removes references to the “European professional card” or “EPC”; “IMI”, and “IMI file”. The EPC is a system of professional qualification validation operated by the European Commission. The IMI is the Internal Market Information system and is the digital system used to process and communicate EPC information and other information about health and social care professionals (e.g. fitness to practice decisions), and an IMI file is a file held on that system. The UK will no longer have access to IMI after exit day, so it will no longer be able to offer or recognise new EPCs or pass on or accept other information via the IMI system.

Part 1 of the Schedule removes references to “national”. Post-exit eligibility for registration will depend on where the qualification is from as opposed to the nationality of the professional.

Part 2 amends and revokes legislation concerned with the regulation of pharmacy professionals in Northern Ireland.

Part 3 of the Schedule saves pending applications in relation to registration made before exit day. Various savings are also made to provide that pre-exit day legislation continues to apply so far as is practically possible after exit day for those who were registered before exit day, or whose applications were pending on exit day.

Part 3 of the Schedule deals with transitional and saving provisions to allow for continued appeals against EPC decisions. The provisions allow individuals to appeal, after exit day against EPC decisions made before exit day and that are within pre-exit day appeal periods, to the PSNI against the effect of the EPC decisions. The PSNI is also obliged to give effect to the decision as far as practically possible without access to IMI. Part 3 of the Schedule does not preserve EPC appeal rights as this is dealt within the Part 1 provisions of the Schedule.

Part 3 of the Schedule contains provisions to allow appeals against “IMI alerts”. An IMI alert is an alert issued through the IMI system about the fitness to practice of a health or social care professional, to relevant European States. Although the United Kingdom’s access to IMI will cease after exit day the regulator will be obliged to notify the European Commission by other means of the outcome of the appeal. Any individual who has an alert issued against them that is still within pre-exit day appeal periods after exit day will be permitted to appeal to the relevant Registering body in the UK against the effect of the alert.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.