Status: This is the original version (as it was originally made).

### SCHEDULES

#### SCHEDULE 2

Pharmacists and pharmacy technicians

### PART 1

#### Amendments to legislation

#### Interpretation

- 1. In this Schedule—
  - (a) "the 1968 Act" means the Medicines Act 1968(1);
  - (b) "the 2010 Order" means the Pharmacy Order 2010(2).

#### **Medicines Act 1968**

2. The 1968 Act is amended as follows.

**3.** In section 67E (interpretation of provisions about defences)(**3**), in the definition of "registrant"—

- (a) in paragraph (a), for "2, 4 or 5" substitute "or 2";
- (b) in paragraph (b), omit the words from "or the register" to "European State".
- 4. In section 69 (general provisions about pharmacies)(4), omit subsection (1ZA).
- 5. In section 71 (business carried on by body corporate)(5), omit subsection (7).
- 6. In section 78 (restrictions on use of titles etc.)(6)—
  - (a) in subsection (5), omit the words from "or in the" to "European State";
  - (b) in subsection (5A), omit "or 4".

#### Pharmacy Order 2010

- 7. The 2010 Order is amended as follows.
- 8. In article 3 (interpretation)(7)—
  - (a) for the definition of "the Directive" substitute—

""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

 <sup>1968</sup> c. 67.
S.I. 2010/231.

<sup>(3)</sup> Section 67E was inserted by S.I. 2018/181.

<sup>(4)</sup> Subsection (1ZA) was inserted by S.I. 2007/3101. Relevant amending instrument is S.I. 2010/231.

<sup>(5)</sup> Subsection (7) was substituted by S.I. 2010/231.

<sup>(6)</sup> Subsections (5) and (5A) were substituted by S.I. 2010/231.

<sup>(7)</sup> Relevant amending instruments are S.I. 2011/1043, 2016/1030.

No 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;";

- (b) omit the definitions of "competent authority", "Directive 2002/58/EC", "European mutual recognition area", "European professional card", "exempt person", "General Systems Regulations", "IMI", "IMI file" and "third country";
- (c) in the definition of "registered pharmacist", omit "or 4";
- (d) in the definition of "registered pharmacy technician", omit "or 5".
- 9. In article 19 (establishment, maintenance of, and access, to the Register), in paragraph (2)-
  - (a) in the words before paragraph (a), for "five" substitute "three";
  - (b) in paragraphs (a) and (b), omit "other than visiting practitioners";
  - (c) at the end of paragraph (b), insert "and";
  - (d) omit sub-paragraph (d) (including the final "and");
  - (e) omit sub-paragraph (e).

10. In article 20 (entitlement to entry in Parts 1 or 2 of the Register), for paragraph (4), substitute—

- "(4) The Registrar must treat a person who—
  - (a) applies to be entered in Part 1 of the Register as a pharmacist,
  - (b) qualified as a pharmacist in a relevant European State,
  - (c) was, on exit day, in the register of pharmaceutical chemists for Northern Ireland, or was entered in that register on or after exit day further to an application made before exit day, and
  - (d) has remained in that register since exit day or, as the case may be, since that entry (disregarding any period in which the person was not in the register as a result of a decision that was later overturned in an appeal or other legal proceeding),

as meeting the requirements of paragraph (1)(a)(i).".

**11.**—(1) Article 21 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacists)(**8**) is amended as follows.

- (2) In paragraph (1)—
  - (a) in sub-paragraph (a), omit the words from "(and" to the end;
  - (b) omit sub-paragraph (b);
  - (c) omit sub-paragraph (c) (but not the final "or");
  - (d) in sub-paragraph (d)—
    - (i) in the words before paragraph (i), omit "subject to paragraph (2),";
    - (ii) omit paragraph (ii)(aa) (including the final "or");
    - (iii) in paragraph (ii)(bb), omit "whether or not P is an exempt person,".
- (3) After paragraph (1), insert—
  - "(1A) A relevant European qualification is to be treated as a qualification which has been approved under paragraph (1)(d)(i).
    - (1B) In this article "relevant European qualification" means-

<sup>(8)</sup> Relevant amending instrument is 2016/1030.

- (a) a qualification that falls within article 21A and has not been designated by the Council for the purposes of this sub-paragraph, or
- (b) a qualification in pharmacy that does not fall within article 21A but—
  - (i) was granted in a relevant European State, and
  - (ii) attests, in the opinion of the Council, to a comparable standard of proficiency to that attested to by a qualification approved under paragraph (1)(a).
- (1C) The Council-
  - (a) may designate a qualification for the purposes of paragraph (1B)(a) only with the approval of the Privy Council;
  - (b) must maintain and publish a list of the qualifications that are so designated.".

(4) Omit paragraphs (2) to (5).

12. After article 21, insert—

#### "European qualifications: pharmacists

**21A.**—(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 paragraph (3) "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.".

**13.**—(1) Article 22 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacy technicians) is amended as follows.

- (2) In paragraph (1)—
  - (a) in sub-paragraph (a), at the end insert "or";
  - (b) omit sub-paragraph (b) (including the final "or");
  - (c) in sub-paragraph (c)—
    - (i) in paragraph (i), omit the final "or";
    - (ii) after paragraph (i), insert-
      - "(ia) holds a qualification which was granted in a relevant European State and, despite its not having been approved under paragraph (i), attests, in the opinion of the Council, to a comparable standard of proficiency to that attested to by a qualification approved under paragraph (1)(a), or";
    - (iii) omit paragraph (ii)(aa);
    - (iv) in paragraph (ii)(bb) omit "whether or not T is an exempt person,".
- (3) Omit paragraphs (2) and (3).

14.—(1) Article 23 (form, manner and content of applications for entry or for renewal of an entry in the register: pharmacists and pharmacy technicians)(9) is amended as follows.

- (2) In paragraph (1)(c)—
  - (a) in paragraph (iii)—

(i) omit "who is not an exempt person";

(ii) at the end insert "and";

- (b) omit paragraph (iv);
- (c) omit paragraph (vi) (including the final "and").
- (3) Omit paragraphs (4) to (11).

**15.** In article 23A (supplementary provisions as to necessary knowledge of English)(10), omit paragraphs (5) and (7).

16.—(1) Article 24 (notification by the Registrar: entry and renewal)(11) is amended as follows.

(2) Omit paragraphs (2A) and (2B).

(3) In paragraph (3), for "specified period" substitute "period of three months beginning with the relevant date".

(4) In paragraph (4)—

- (a) omit sub-paragraph (a) (including the final "or");
- (b) in the words after sub-paragraph (b)—
  - (i) omit the words from "a decision", where it first occurs, to "or";
  - (ii) omit "(as the case may be)";
  - (iii) for "specified period" substitute "period of three months beginning with the relevant date".
- (5) Omit paragraph (5).

(6) In paragraph (5A), for "any period of time for the purposes of paragraph (5)" substitute "the period of three months for the purposes of paragraph (3) or (4)".

**17.** In article 29 (corrections to the Register), in paragraph (3)(a), omit "or in Part 4 or 5 of the Register".

18. In article 32 (indemnity arrangements)(12), omit paragraph (11).

**19.** Omit article 33 (visiting pharmacists and pharmacy technicians from relevant European States).

20. Omit article 33A (European professional card)(13).

21. In article 36 (fees in connection with entry)—

- (a) in paragraph (1), for "Subject to paragraph (3), the" substitute "The";
- (b) omit paragraph (3).

22. In article 37 (restoration to the Register), in paragraph (5), for ", 2, 4 or 5" substitute "or 2".

<sup>(9)</sup> Relevant amending instrument is S.I. 2016/1030.

<sup>(10)</sup> Article 23A was inserted by S.I. 2015/806.

<sup>(11)</sup> Paragraphs (2A), (2B) and (5A) were inserted, and paragraphs (4) and (5) were amended, by S.I. 2015/806.

<sup>(12)</sup> Article 32 was substituted by S.I. 2014/1887.

<sup>(13)</sup> Article 33A was inserted by S.I. 2016/1030. Relevant amendments made by paragraph 354 of Schedule 19 to the Data Protection Act 2018.

- **23.**—(1) Article 38 (offences relating to the Register) is amended as follows.
- (2) In paragraph (2)—
  - (a) in sub-paragraph (a), omit "or 4";
  - (b) in sub-paragraph (b), omit "or 5".
- (3) In paragraph (4)—
  - (a) in sub-paragraph (a), omit "or 4";
  - (b) in sub-paragraph (b), omit "or 5".

24.—(1) Article 39 (appealable decisions)(14) is amended as follows.

- (2) In paragraph (1)—
  - (a) omit sub-paragraphs (a), (c), (cb) and (e);
  - (b) in sub-paragraphs (i) and (l), for ", 2, 4 or 5" substitute "or 2";
  - (c) omit sub-paragraphs (t) and (u).
- (3) Omit paragraph (1A).

25. In article 40 (appeals to the Appeals Committee)(15)—

- (a) omit paragraph (1A);
- (b) in paragraph (2), omit sub-paragraph (b) (together with the "or" before it);
- (c) in paragraph (7)—
  - (i) in sub-paragraph (b), omit the words from "or, in" to the end;
  - (ii) omit sub-paragraph (ca) (but not the final "or").
- 26. In article 41 (appeals from the Appeals Committee)(16), in paragraph (4)—
  - (a) in sub-paragraph (b), omit the words from "or, in" to the end;
  - (b) omit sub-paragraph (ca) (but not the final "or").

**27.** In article 42 (education, training and acquisition of experience)(17), in paragraph (1)(a), omit from "except" to "22(1)(b),".

**28.** Omit article 42A (professional traineeships carried out in other relevant European States, etc)(**18**).

29. In article 43 (continuing professional development)—

- (a) omit paragraph (5)(c);
- (b) omit paragraph (8)(b);
- (c) omit paragraph (9).

**30.** In article 66 (rules), omit paragraph (2).

- 31. Omit article 67 (The Directive: designation of competent authority etc)(19).
- **32.** Omit article 71 (review)(**20**).

<sup>(14)</sup> Paragraph (1)(cb) was inserted by S.I. 2015/806. Paragraph (1)(t) and (u) and (1A) were inserted by S.I. 2016/1030.

<sup>(15)</sup> Paragraphs (1A) and (7)(ca) were inserted by, and paragraph (7)(b) was amended by, S.I. 2016/1030.

<sup>(16)</sup> Paragraph (4)(ca) was inserted by, and paragraph (4)(b) was amended by, S.I. 2016/1030.

<sup>(17)</sup> Relevant amending instrument is S.I. 2016/1030.

<sup>(18)</sup> Article 42A was inserted by S.I.2016/1030.

<sup>(19)</sup> Relevant amendments made by paragraph 357 of Schedule 19 to the Data Protection Act 2018, S.I. 2016/1030.

**33.** Omit Schedule 2 (visiting pharmacists and pharmacy technicians from relevant European States)(**21**).

- 34. Omit Schedule 2A (European professional card)(22).
- 35. Omit Schedule 3 (The Directive: designation of competent authority etc)(23).

#### Medicines for Human Use (Clinical Trials) Regulations 2004

**36.** In the Medicines for Human Use (Clinical Trials) Regulations 2004(**24**), in regulation 2(1) (interpretation), in the definition of "pharmacist"—

- (a) in paragraph (a), omit "or 4";
- (b) in paragraph (b), omit the words from ", or the" to "European State,".

#### **Approved European Pharmacy Qualifications Order of Council 2007**

**37.** The Approved European Pharmacy Qualifications Order of Council 2007(25) is revoked.

#### National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

**38.** In the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009(**26**), in regulation 2 (interpretation), in paragraph (1), in the definition of "pharmacist", omit "or 4".

#### **General Pharmaceutical Council (Registration) Rules 2010**

**39.**—(1) The General Pharmaceutical Council (Registration) Rules 2010(27) are amended as follows.

- (2) In rule 10 (entry in the Register)—
  - (a) in paragraph (3)—
    - (i) omit sub-paragraphs (e), (f), (h) and (i);
    - (ii) in sub-paragraph (j)—
      - (aa) omit paragraph (i) (including the final "or");
      - (bb) in paragraph (ii), omit from "in", where it first occurs, to "way),";
    - (iii) in sub-paragraph (k)—
      - (aa) omit paragraph (i) (including the final "and");
      - (bb) in paragraph (ii), omit "whether or not the applicant is an exempt person,";
  - (b) omit paragraph (3ZA);
  - (c) in paragraph (12), omit the definition of "attesting state" (including the final "and").
- (3) In the heading to Part 4, for ", 2, 4 and 5" substitute "and 2".
- (4) In rule 18 (notice of intention to remove: stage 1)—

<sup>(21)</sup> Relevant amending instrument is S.I. 2016/1030.

<sup>(22)</sup> Schedule 2A was inserted by S.I. 2016/1030. Relevant amendments made by paragraph 358 of Schedule 19 to the Data Protection Act 2018.

<sup>(23)</sup> Relevant amendments made by paragraph 359 of Schedule 19 to the Data Protection Act 2018, S.I. 2015/806, 2016/1030.

<sup>(24)</sup> S.I. 2004/1031. Paragraph (a) was substituted by S.I. 2010/231, and paragraph (b) was amended by, S.R. 2008 No.192.

<sup>(</sup>**25**) S.I. 2007/564.

<sup>(26)</sup> S.S.I. 2009/183. Relevant amending instrument is S.I. 2010/231.

<sup>(27)</sup> As set out in the Schedule to the General Pharmaceutical Council (Registration Rules) Order of Council 2010 (S.I. 2010/1617). Paragraph 10(3ZA) was inserted by S.I. 2016/1030. Paragraph 10(12) was substituted by S.I. 2010/2660. Relevant amending instruments are S.I. 2012/3171, 2016/1008, 1030.

- (a) in paragraph (1)(a), omit ", 4 or 5";
- (b) in paragraph (5)(a)(i), omit ", 4 or 5".
- (5) In rule 19 (subsequent action by Registrar: stage 2)—
  - (a) in paragraph (1), omit ", 4 or 5";
  - (b) in paragraph (4)(a), omit ", 4 or 5";
  - (c) in paragraph (5)(b), omit ", 4 or 5".
- (6) In rule 20 (decisions in contested cases: stage 3), in paragraph (3)(a), omit ", 4 or 5".

#### Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010

**40.** The Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010(**28**) is revoked.

## General Pharmaceutical Council (Continuing Professional Development and Consequential Amendments) Rules 2011

**41.**—(1) The General Pharmaceutical Council (Continuing Professional Development and Consequential Amendments) Rules 2011(**29**) are amended as follows.

- (2) In rule 5 (steps which the Registrar may take)—
  - (a) in paragraph (2)(b), for ", 2, 4 or 5" substitute "or 2";
  - (b) omit paragraph (3).
- (3) In rule 6 (remedial measures), in paragraph (1)(f), omit paragraph (ii) and the "or" before it.

(4) In rule 8 (subsequent action by the Registrar: stage 2), in paragraph (1), for ", 2, 4 or 5" substitute "or 2".

(5) In rule 9 (decisions in contested cases: stage 3), in paragraph (5), for ", 2, 4 or 5" substitute "or 2".

(6) In rule 11 (suspension from the register pending appeal), in paragraph (1)(a), for ", 2, 4 or 5" substitute "or 2".

#### **Human Medicines Regulations 2012**

42. In the Human Medicines Regulations 2012(30), in regulation 8(1) (interpretation)—

- (a) in the definition of "health care professional", in paragraph (d), omit "or 5";
- (b) in the definition of "pharmacist"—
  - (i) in paragraph (a), omit "or 4";
  - (ii) in paragraph (b), omit the words from "or the" to "European State".

# National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

**43.** In the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(31), in regulation 2(1)—

(a) in the definition of "registered pharmacist", omit "or 4";

<sup>(28)</sup> S.I. 2010/1620.

<sup>(29)</sup> As set out in the Schedule to the General Pharmaceutical Council (Continuing Professional Development and Consequential Amendments) Rules Order of Council 2011 (S.I. 2011/1367).

**<sup>(30)</sup>** S.I. 2012/1916.

<sup>(</sup>**31**) S.I. 2013/349.

(b) in the definition of "registered pharmacy technician", omit "or 5".