

2016 No. 372

HEALTH CARE AND ASSOCIATED PROFESSIONS

**The Pharmacy (Premises Standards, Information Obligations,
etc.) Order 2016**

Made - - - - *15th March 2016*

Coming into force in accordance with article 1(2) to (4)

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At the Court at Buckingham Palace, the 15th day of March 2016

Present,

The Queen's Most Excellent Majesty in Council

This Order in Council is made in exercise of the powers conferred by sections 60(1)(a), (2)(aa), (2A)(a) to (c), (2B) and (4) and 62(4) and (4A) of, and paragraphs 1, 2, 3, 5 and 6 of Schedule 3 to, the Health Act 1999(a).

The Secretary of State and the Scottish Ministers published a draft of this Order in Council and invited representations as required by paragraph 9(1) and (3) of Schedule 3 to the Health Act 1999.

The period of three months mentioned in paragraph 9(4) of that Schedule expired before a draft of this Order in Council, together with a report about the consultation, was laid before Parliament and the Scottish Parliament.

A draft of this Order in Council has been approved by resolution of each House of Parliament and of the Scottish Parliament in accordance with section 62(10) of the Health Act 1999.

Accordingly, Her Majesty is pleased, by and with the advice of Her Privy Council, to make the following Order in Council:

(a) 1999 c. 8. Section 60 has been amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act"), section 26(9); the Health and Social Care Act 2008 (c. 14) ("the 2008 Act"), Schedule 8, paragraph 1, and Schedule 10, paragraph 10; the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 209, 210 and 213(7)(i), and Schedule 15, paragraphs 60 and 72(2); and S.I. 2002/253 and 254, 2010/231 and 2012/1916. Section 62 has been amended by: the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 194 and 197, and Schedule 4, paragraph 1; and the 2008 Act, Schedule 8, paragraph 2, and Schedule 10, paragraph 11. Schedule 3 has been amended by: the 2002 Act, section 26(10); the Health and Social Care (Community Health and Standards) Act 2003 (c. 43), Schedule 11, paragraph 67, and Schedule 14, Part 4; the Health Act 2006 (c. 28), section 33 and Schedule 9; the 2008 Act, Schedule 8, paragraphs 3 to 10; the 2012 Act, section 211 and Schedule 15, paragraphs 61 and 72(4); and S.I. 2002/254.

PART 1

General provisions

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016.

(2) This Part comes into force on the twenty-eighth day after the day on which this Order is made.

(3) Except as provided for by paragraph (2), this Order comes into force on such days as the Privy Council may by order appoint.

(4) Different days may be appointed under paragraph (3) for different purposes.

(5) In this Order—

“the 1968 Act” means the Medicines Act 1968(a);

“the 1976 Order” means the Pharmacy (Northern Ireland) Order 1976(b); and

“the 2010 Order” means the Pharmacy Order 2010(c).

Extent

2.—(1) Subject to paragraph (2), this Order extends to England and Wales, Scotland and Northern Ireland.

(2) Part 3 extends only to Northern Ireland and Part 4 extends only to England and Wales and Scotland.

Transitional, transitory and saving provisions

3.—(1) In connection with the commencement of any provision of this Order, the Privy Council may by order make such transitional, transitory or saving provisions as it considers appropriate.

(2) The power to make an order under paragraph (1) may be exercised—

(a) so as to make different provision—

(i) for different areas,

(ii) with respect to different cases or different classes of cases, and

(iii) in respect of the same case or class of case for different purposes;

(b) in relation to all cases to which the power extends or in relation to those cases subject to specified exceptions; and

(c) so as to make any supplementary, incidental or consequential provisions which the Privy Council considers necessary or expedient.

Privy Council procedures and legislative procedures

4.—(1) Any power vested in the Privy Council to make an order under this Part may be exercised by any two or more members of the Privy Council.

(2) Any power of the Privy Council to make an order under this Part is exercisable by statutory instrument, and for the purposes of section 1 of the Statutory Instruments Act 1946(d) (definition

(a) 1968 c. 67.

(b) S.I. 1976/1213 (N.I. 22).

(c) S.I. 2010/231.

(d) 1946 c. 36. Section 1(1A) was inserted by the Government of Wales Act 1998 (c. 38), Schedule 12, paragraph 2, and substituted by the Government of Wales Act 2006 (c. 32), Schedule 10, paragraph 2.

of “Statutory Instrument”), any power of the Privy Council to make an order under this Part is to be taken to be conferred by an Act of Parliament.

(3) Before making an order under this Part that includes measures relating to the regulation of pharmacy technicians, the Privy Council must consult the Scottish Ministers.

(4) An order made (wholly or partly) under article 3(1) is subject to annulment by resolution of either House of Parliament.

(5) If an order of the description given in paragraph (4) includes measures relating to the regulation of pharmacy technicians in Scotland—

- (a) that order is in addition subject to the negative procedure in the Scottish Parliament; and
- (b) sections 28 and 31 of the Interpretation and Legislative Reform (Scotland) Act 2010(a) (negative procedure etc.) apply in relation to the order as they apply in relation to devolved subordinate legislation (within the meaning of Part 2 of that Act) that is subject to the negative procedure, but as if references to a Scottish statutory instrument were references to a statutory instrument.

(6) Before making an order under article 1(3) that commences—

- (a) an amendment of the 1968 Act as it applies in Northern Ireland; or
- (b) a provision of Part 3,

the Privy Council must obtain the agreement of the Minister for Health, Social Services and Public Safety to the making of the order.

(7) Any act of the Privy Council under this Part is sufficiently signified by an instrument signed by the Clerk of the Privy Council.

(8) Where an order of the Privy Council under this Part is signified by an instrument purporting to be signed by the Clerk of the Privy Council, that is evidence and in Scotland sufficient evidence of—

- (a) the fact that the order was duly made; and
- (b) the order’s terms.

PART 2

Amendments to the Medicines Act 1968

Amendment of section 74 of the 1968 Act

5.—(1) Section 74 of the 1968 Act(b) (meaning of “registered pharmacy”) is amended as follows.

(2) In subsection (1A)—

- (a) for “paragraph (4)(b) of article 14” substitute “section 82A of this Act(c), paragraph 8 of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976(d) or article 14(4)(b) or 56(e)”;
- (b) omit “of that Order”; and
- (c) after “by rules” insert “in relation to Great Britain or the Council of the Pharmaceutical Society of Northern Ireland may prescribe by regulations in relation to Northern Ireland”.

(3) In subsection (1B), for “apart from that Order” substitute “except for a purpose prescribed by the rules or regulations mentioned in subsection (1A)”.

(a) 2010 asp 10.

(b) Section 74 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1(12), paragraph 1, and by S.I. 2010/231.

(c) Section 82A is inserted by article 11 of this Order.

(d) Schedule 3 was substituted by S.R. 2012/308.

(e) Articles 14 and 56 are amended by articles 23 and 25 of this Order respectively.

Amendment of section 74B of the 1968 Act

6. In section 74B of the 1968 Act(**a**) (conditions for registration: Great Britain), in subsection (5)—

- (a) in paragraph (a), for “provided for in rules made” substitute “set”; and
- (b) in paragraph (b)—
 - (i) in sub-paragraph (i), for “provided for in rules made” substitute “set”, and
 - (ii) in sub-paragraph (ii), after “of rules” insert “(if any)”.

Amendment of section 74H of the 1968 Act

7. In section 74H of the 1968 Act(**b**) (change of ownership of retail pharmacy business: Great Britain), in subsection (6)(c), for “provided for in rules made” substitute “set”.

Amendment of section 75 of the 1968 Act

8. In section 75 of the 1968 Act(**c**) (registration of premises: Northern Ireland), omit subsections (4) to (6).

Amendment of section 80 of the 1968 Act

9.—(1) Section 80 of the 1968 Act(**d**) (power for relevant disciplinary committee to disqualify and direct removal from register) is amended as follows.

(2) In subsection (1)(c)—

- (a) omit “in Great Britain”;
- (b) after “premises at” insert “or from”;
- (c) for “provided for in rules made under” substitute “set under Article 5A(1) of the Pharmacy (Northern Ireland) Order 1976(**e**) or”; and
- (d) after “business at” insert “or from”.

(3) After subsection (1), insert the following subsections—

“(1A) Where—

- (a) a pharmacist or partnership carries on a retail pharmacy business, and
- (b) in respect of premises that are entered in the register as premises at or from which that pharmacist or partnership carries on that business, there is a failure to meet the standards that are set under Article 5A(1) of the Pharmacy (Northern Ireland) Order 1976 or article 7(1) of the Pharmacy Order 2010(**f**) in connection with the carrying on of the business at or from those premises,

then, subject to the following provisions of this Part of this Act, the relevant disciplinary committee, after inquiring into the case, may direct that the pharmacist or partnership is to be disqualified for the purposes of this Part of this Act.

(1B) But, in a case falling within subsection (1)(c) or (1A), the relevant disciplinary committee may only give a direction under the subsection in question if they are satisfied that the body corporate, the pharmacist or the partnership is unfit to carry on a retail pharmacy business safely and effectively, so far as concerns—

- (a) the retail sale of medicinal products (whether they are on a general sale list or not),
or

(a) Section 74B was inserted by S.I. 2010/231.
(b) Section 74B was inserted by S.I. 2010/231.
(c) Section 75 has been amended by S.I. 2010/231.
(d) Section 80 has been amended by S.I. 2007/289 and 2010/231.
(e) Paragraph 5A is inserted by article 13 of this Order.
(f) Article 7(1) is substituted by article 19(2) of this Order.

- (b) the supply of such products in circumstances corresponding to retail sale.”.
- (4) In subsection (2)—
 - (a) for “within the preceding subsection” substitute “within subsection (1) or (1A)”;
 - (b) in paragraph (a)—
 - (i) for “that subsection” substitute “the subsection in question”,
 - (ii) after “premises at” insert “or from”, and
 - (iii) after “body corporate” insert “, the pharmacist or the partnership”; and
 - (c) in paragraph (b), for “the preceding subsection” substitute “the subsection in question”.
- (5) After subsection (2), insert the following subsection—

“(2A) But, in a case falling within subsection (1)(c) or (1A), the relevant disciplinary committee may only direct the registrar under subsection (2)(b) to remove premises from the register if they are satisfied that the body corporate, the pharmacist or the partnership is unfit to carry on a retail pharmacy business safely and effectively at or from those premises, so far as concerns—

 - (a) the retail sale of medicinal products (whether they are on a general sale list or not), or
 - (b) the supply of such products in circumstances corresponding to retail sale.”.
- (6) In subsection (3)—
 - (a) after “subsection (1)” insert “or (1A)”;
 - (b) for “the last preceding subsection”, at each place where it occurs, substitute “subsection (2)”.

Amendment of section 82 of the 1968 Act

- 10.** In section 82 of the 1968 Act(a) (procedure relating to disqualification)—
- (a) in subsection (2), after “body corporate” insert “, pharmacist, partnership”; and
 - (b) in subsection (3), after “body corporate” insert “, pharmacist, partnership”.

New section 82A of the 1968 Act

11. After section 82 of the 1968 Act (procedure relating to disqualification), insert the following section—

“Interim measures

82A.—(1) Subsection (2) applies where—

- (a) the relevant disciplinary committee have given a direction (“the principal direction”) under section 80(1), (1A) or (2) in relation to a body corporate, pharmacist or partnership; and
- (b) the direction has not yet taken effect.

(2) Where the committee are satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest, the committee may direct the registrar to suspend from the register, until the principal direction takes effect or an appeal under section 82(3) against the principal direction is successful—

- (a) all entries of premises entered in the register as premises at or from which the body corporate, pharmacist or partnership carries on a retail pharmacy business; or

(a) Amended by the Constitutional Reform Act 2005 (c. 4), Schedule 11, paragraph 6(1), and by S.I. 2007/289 and 2012/1916.

- (b) entries of such of those premises as may be specified in the direction under this subsection.
- (3) Where the committee give a direction under subsection (2), the registrar must send to the body corporate, pharmacist or partnership to whom the direction relates a statement in writing giving that person notice of—
 - (a) the contents of the direction; and
 - (b) the right of appeal under subsection (5).
- (4) The statement must be sent—
 - (a) in the case of a body corporate, to the body corporate at its registered or principal office;
 - (b) in the case of a pharmacist, to the pharmacist at the pharmacist’s home address in the register;
 - (c) in the case of a partnership, to the partnership at its principal office.
- (5) A body corporate, pharmacist or partnership to whom a direction under subsection (2) relates may appeal against the direction to the High Court.
- (6) Subsections (4) to (6) of section 82 apply in relation to an appeal under subsection (5) as they apply in relation to an appeal under section 82(3).
- (7) Subsections (7) and (8) of section 82 apply in the application of this section to Scotland or Northern Ireland as they apply in the application of section 82 to Scotland or Northern Ireland.”.

New section 84B of the 1968 Act

12. After section 84A of the 1968 Act(a) (rules by the General Pharmaceutical Council), insert the following section—

“Regulations by the Council of the Pharmaceutical Society of Northern Ireland

84B. The provisions of Article 25A of the Pharmacy (Northern Ireland) Order 1976(b) apply to the making of regulations by the Council of the Pharmaceutical Society of Northern Ireland under this Part as they apply to the making of regulations by that Council under that Order.”.

PART 3

Amendments to the Pharmacy (Northern Ireland) Order 1976

New Article 5A of the 1976 Order

13. After Article 5 of the 1976 Order(c) (regulations made by the Council: general), insert the following Article—

“Premises standards

5A.—(1) The Council shall set standards that are to be met in connection with the carrying on of a retail pharmacy business at or from a registered pharmacy by the person carrying on that business.

(2) The standards may, in particular, relate to—

(a) Section 84A was inserted by S.I. 2010/231.
 (b) Article 25A was inserted by S.R. 2012/308.
 (c) Article 5 was amended, and its heading substituted, by S.R. 2012/308.

- (a) governance arrangements for registered pharmacies, including arrangements for managing and monitoring the safe and effective provision of pharmacy services at or from registered pharmacies;
- (b) the working environment at and the condition of registered pharmacies;
- (c) the patient and public experience of pharmacy services provided at or from registered pharmacies;
- (d) the condition of the equipment and facilities used in the provision of pharmacy services at or from registered pharmacies;
- (e) the working environment at and condition of associated premises and the condition of equipment and facilities at associated premises (being premises at which activities are carried on which are integral to the provision of pharmacy services at or from registered pharmacies), but only to the extent appropriate for ensuring the safe and effective provision of pharmacy services at or from registered pharmacies;
- (f) training of staff of the retail pharmacy business;
- (g) arrangements for ensuring staff of the retail pharmacy business—
 - (i) have the authority and ability to act to ensure, and
 - (ii) are properly held accountable for,
 the health, safety and well-being of patients to whom pharmacy services are provided at or from registered pharmacies, and of other persons at registered pharmacies.

(2) The Council shall publish the standards set under this article, as they exist from time to time, in such manner as it considers appropriate.”.

Amendment of Article 20 of the 1976 Order

14. In Article 20 of the 1976 Order(a) (fitness to practise), after “and proceedings” insert “(including, where applicable, proceedings in relation to a person carrying on a retail pharmacy business)”.

Amendment of paragraph 8 of Schedule 3 to the 1976 Order

15.—(1) Paragraph 8 of Schedule 3 to the 1976 Order(b) (fitness to practise – interim orders) is amended as follows.

(2) In sub-paragraph (1)(a), omit “(an “interim suspension order”)”.

(3) After sub-paragraph (1) insert the following sub-paragraphs—

“(1A) Where, during an inquiry under section 80(1) or (1A) of the Medicines Act, the Statutory Committee is satisfied that it is necessary for the protection of the public or is otherwise in the public interest to suspend one or more of the entries in the premises register relating to a person carrying on a retail pharmacy business (“a pharmacy owner”), the Committee may make an order that the entry (or entries) in question be suspended for such period not exceeding 18 months as may be specified in the order.

(1B) In this paragraph—

“interim suspension order” means an order under sub-paragraph (1)(a) or (1A); and

“premises register” means the register kept for the purposes of section 75 of the Medicines Act(c) (registration of premises: Northern Ireland).”.

(4) In sub-paragraph (2)—

(a) after “sub-paragraph (1)” insert “or (1A)”; and

(a) Substituted by S.R. 2012/308.

(b) Schedule 3 was inserted by S.R. 2012/308.

(c) Section 75 has been amended by S.I. 2010/231 and is amended by article 8.

- (b) in paragraph (a)(ii), for “the person concerned” substitute “the registered person or pharmacy owner concerned”.
- (5) In sub-paragraph (3)—
 - (a) for “to any person” substitute “to any registered person or pharmacy owner”; and
 - (b) in paragraph (c), before “if satisfied that” insert “as regards a registered person,”.
- (6) For sub-paragraph (4) substitute—

“(4) If an order is made, revoked or varied under any provision of this paragraph, the registrar must without delay send to the registered person or pharmacy owner in respect of whose entry in the register or the premises register it relates a statement in writing giving the registered person or pharmacy owner notice of the order, the revocation or, as the case may be, the variation.”.
- (7) In sub-paragraph (5), after “sub-paragraph (1)” insert “, (1A)”.
- (8) In sub-paragraph (8), after “a registered person” insert “or pharmacy owner”.
- (9) In sub-paragraph (10), for “any person” substitute “a registered person”.
- (10) After sub-paragraph (10), insert the following sub-paragraph—

“(10A) At the conclusion of an inquiry under section 80(1) or (1A) of the Medicines Act, if an interim suspension order remains in effect in relation to the pharmacy owner who was the subject of the inquiry, the Statutory Committee must revoke the order whether or not a direction is given in relation to the pharmacy owner under that section.”.

Amendment of paragraph 15 of Schedule 3 to the 1976 Order

- 16.** In paragraph 15 of Schedule 3 to the 1976 Order(a) (fitness to practise – regulations in respect of proceedings)—
- (a) in sub-paragraph (2)(b), after “individual who, or” insert “partnership or”; and
 - (b) in sub-paragraph (3)—
 - (i) in paragraph (d)(i), after “the individual”, at both places, insert “, partnership”, and
 - (ii) in paragraph (j)(i), after “the individual”, at both places, insert “, partnership”.

PART 4

Amendments to the Pharmacy Order 2010

Amendment of article 3 of the 2010 Order

- 17.** In article 3 of the 2010 Order(b) (interpretation), in paragraph (1), omit the definition of “Registrar General”.

Amendment of article 5 of the 2010 Order

- 18.** In article 5 of the 2010 Order (standards and requirements: consultation and review), after paragraph (1) insert the following paragraph—

“(1A) Before setting any standards under this Order, the Council must consult the Scottish Ministers, the Welsh Ministers and the Secretary of State for Health.”.

Amendment of article 7 of the 2010 Order

- 19.**—(1) Article 7 of the 2010 Order (standards: general) is amended as follows.

(a) Schedule 3 was inserted by S.R. 2012/308.
 (b) Amended by S.I. 2011/1043 and 2015/806 and 968.

(2) For paragraph (1) substitute—

“(1) In the exercise of its functions under article 4(3)(b), the Council must set standards that are to be met in connection with the carrying on of a retail pharmacy business at or from a registered pharmacy by the person carrying on that business.”.

(3) Omit paragraph (2).

(4) For paragraph (3) substitute—

“(3) The standards may, in particular, relate to—

- (a) governance arrangements for registered pharmacies, including arrangements for managing and monitoring the safe and effective provision of pharmacy services at or from registered pharmacies;
- (b) the working environment at and the condition of registered pharmacies;
- (c) the patient and public experience of pharmacy services provided at or from registered pharmacies;
- (d) the condition of the equipment and facilities used in the provision of pharmacy services at or from registered pharmacies;
- (e) the working environment at and condition of associated premises and the condition of equipment and facilities at associated premises (being premises at which activities are carried on which are integral to the provision of pharmacy services at or from registered pharmacies), but only to the extent appropriate for ensuring the safe and effective provision of pharmacy services at or from registered pharmacies;
- (f) training of staff of the retail pharmacy business;
- (g) arrangements for ensuring staff of the retail pharmacy business—
 - (i) have the authority and ability to act to ensure, and
 - (ii) are properly held accountable for,the health, safety and well-being of patients to whom pharmacy services are provided at or from registered pharmacies, and of other persons at registered pharmacies.”.

(5) In paragraph (4)—

(a) for “must also” substitute “may”; and

(b) in sub-paragraph (b)—

(i) omit “or” at the end of paragraph (i),

(ii) after paragraph (i) insert the following paragraph—

“(ia) on or within a specified period after the occurrence of any event (which includes a decision that an event is to occur) of a description specified in the rules, or”, and

(iii) for paragraph (ii) substitute the following paragraph—

“(ii) on such dates or at such intervals as may be specified in the rules or the Council may determine (whether generally, in relation to a description of persons carrying on a retail pharmacy business or in relation to particular persons carrying on such a business); and”.

(6) In paragraph (5)—

(a) for “must,” substitute “may,”; and

(b) for sub-paragraph (c), substitute—

“(c) where medicinal products are sold by retail, or supplied in circumstances corresponding to retail sale, at or from premises of a body corporate that is carrying on a retail pharmacy business at or from those premises, the name and home address of the superintendent pharmacist of that business;”.

(7) In paragraph (6)—

- (a) in sub-paragraph (a)—
 - (i) in paragraph (i), after “charged” insert “or for which that individual has been cautioned”,
 - (ii) in paragraph (ii), for “has been charged” substitute “or the partnership (whether or not as an entity separate from the partners) has been charged or for which the partner or partnership has been cautioned”, and
 - (iii) in paragraph (iii), for “has been charged” substitute “or (if not a director) its superintendent pharmacist has been charged or for which the body corporate, a director or the superintendent pharmacist has been cautioned”; and
 - (b) in sub-paragraph (b)—
 - (i) in paragraph (ii), after “a partnership,” insert “the partnership or”, and
 - (ii) in paragraph (iii), after “any director” insert “or (if not a director) the superintendent pharmacist”.
- (8) Omit paragraph (7).

Amendment of article 8 of the 2010 Order

20. In article 8 of the 2010 Order(a) (the inspectorate), in paragraph (2)(a), for “may be provided for by rules” substitute “are set”.

Amendment of article 9 of the 2010 Order

21. In article 9 of the 2010 Order (inspection and enforcement), after paragraph (2) insert the following paragraphs—

“(3) The Council may, in such manner as it sees fit, publish reports of routine inspections, special inspections and other visits to registered pharmacies by inspectors, and the reports may include an account of the outcomes of those inspections and visits.

(4) If a report that the Council proposes to publish pursuant to paragraph (3) includes personal data, it is to be assumed for the purposes of section 35(1) of the Data Protection Act 1998(b) (disclosure required by law etc.) that the disclosure of personal data is required by that paragraph.”.

Amendment of article 13 of the 2010 Order

22.—(1) Article 13 of the 2010 Order (improvement notices) is amended as follows.

(2) In paragraph (1)—

- (a) after “retail pharmacy business at”, at both places, insert “or from”;
- (b) in sub-paragraph (a), for “provided for in rules made” substitute “set”;
- (c) omit “or” at the end of sub-paragraph (a);
- (d) in sub-paragraph (b), for “Britain,” substitute “Britain); or”;
- (e) after sub-paragraph (b) insert—

“(c) a failure to comply with a requirement contained in any rules made under article 7(4),”.

(3) In paragraph (2)(a), for “paragraph (1)(a) or (b)” substitute “paragraph (1)”.

(a) Amended by S.I. 2015/968.
 (b) 1998 c. 29.

Amendment of article 14 of the 2010 Order

23.—(1) Article 14 of the 2010 Order (non-compliance with improvement notices) is amended as follows.

(2) In paragraph (1), after “retail pharmacy business at” insert “or from”.

(3) After paragraph (1) insert the following paragraph—

“(1A) But no offence is committed if the failure to comply with the terms of an improvement notice relates to matters included in the improvement notice—

(a) pursuant to article 13(1)(a); or

(b) pursuant to article 13(1)(b), if the failure is to comply with standards set under article 7(1) that the Registrar has made a condition of the entry of the registered premises in the Register pursuant to section 74D of the Medicines Act 1968(a) (conditional registration: Great Britain).”.

(4) In paragraph (2), after “retail pharmacy business at” insert “or from”.

(5) After paragraph (4) insert the following paragraph—

“(4A) But if the failure to comply with terms of the improvement notice relates to matters included in the improvement notice—

(a) pursuant to article 13(1)(a); or

(b) pursuant to article 13(1)(b), if the failure is to comply with standards set under article 7(1) that the Registrar has made a condition of the entry of the registered premises in the Register pursuant to section 74D of the Medicines Act 1968,

the Registrar must instead refer the matter for consideration by the Fitness to Practise Committee under section 80(1)(c) or (1A) of the Medicines Act 1968(b) (grounds for disqualification in certain cases).”.

Amendment of article 29 of the 2010 Order

24. In article 29 of the 2010 Order (corrections to the Register), for paragraph (2) substitute the following paragraph—

“(2) On registering the death of a registrant—

(a) in England and Wales, a registrar of births and deaths; or

(b) in Scotland, a district registrar,

must, without charge, send forthwith to the Registrar a certified copy of the entry in the register of deaths relating to the death.”.

Amendment of article 56 of the 2010 Order

25.—(1) Article 56 of the 2010 Order (interim orders) is amended as follows.

(2) In paragraph (1)(a), omit “(an “interim suspension order”)”.

(3) After paragraph (1) insert the following paragraphs—

“(1A) Where, during an inquiry under section 80(1) or (1A) of the Medicines Act 1968, the Fitness to Practise Committee is satisfied that it is necessary for the protection of the public or is otherwise in the public interest to suspend one or more of the entries in Part 3 of the register relating to a person carrying on a retail pharmacy business (“a pharmacy owner”), the Committee may make an order that the entry (or entries) in question be suspended for such period not exceeding 18 months as may be specified in the order.

(1B) In this article, an “interim suspension order” means an order under paragraph (1)(a) or (1A).”.

(a) Section 74D was inserted by S.I. 2010/231.

(b) Subsection (1) was substituted by S.I. 2010/231.

- (4) In paragraph (2)—
- (a) after “paragraph (1)” insert “or (1A)”; and
 - (b) in sub-paragraph (a)(ii), for “the person” substitute “the registrant or pharmacy owner”;
- (5) In paragraph (3)—
- (a) for “to any person” substitute “to any registrant or pharmacy owner”; and
 - (b) in sub-paragraph (c), before “if satisfied that” insert “as regards a registrant,”.
- (6) In paragraph (4)—
- (a) for “to the person” substitute “to the registrant or pharmacy owner”;
 - (b) after “home address of that person” insert “, or in the case of pharmacy owner that is a partnership or body corporate at the address of its registered or principal office,”; and
 - (c) for “giving the person” substitute “giving the registrant or pharmacy owner”.
- (7) In paragraph (5), after “paragraph (1)” insert “, (1A)”.
- (8) In paragraph (8), after “a registrant” insert “or pharmacy owner”.
- (9) In paragraph (10)—
- (a) for “any person” substitute “a registrant”;
 - (b) for “that person” substitute “the registrant”; and
 - (c) for “the person’s” substitute “the registrant’s”.
- (10) After paragraph (10) insert the following paragraph—
- “(10A) At the conclusion of an inquiry under section 80(1) or (1A) of the Medicines Act 1968, if an interim suspension order remains in effect in relation to the pharmacy owner who was the subject of the inquiry, the Fitness to Practise Committee must revoke the order whether or not a direction is given in relation to the pharmacy owner under that section.”.

Amendment of article 61 of the 2010 Order

- 26.** In article 61 of the 2010 Order (a) (rules in respect of proceedings)—
- (a) in paragraph (2)(b), after “individual who, or” insert “partnership or”; and
 - (b) in sub-paragraph (3)—
 - (i) in paragraph (d)(i), after “the individual”, at both places, insert “, partnership”, and
 - (ii) in paragraph (j)(i), after “the individual”, at both places, insert “, partnership”.

Ceri King
Deputy Clerk of the Privy Council

EXPLANATORY NOTE

(This note is not part of the Order)

This Order, principally, makes provision relating to the setting of standards for the safe and effective practice of pharmacy at registered pharmacies, and relating to the enforcement of those standards. Pharmacies have to be registered in the United Kingdom if a retail pharmacy business is carried on at those premises. In Great Britain they are registered by the General Pharmaceutical Council (GPhC) and in Northern Ireland by the Pharmaceutical Society of Northern Ireland (PSNI).

Part 1 contains general provisions, including powers to make commencement and transitional provisions orders and the procedural requirements relating to them.

(a) Amended by S.I. 2015/806.

The powers of the GPhC to set standards (“premises standards”) in connection with the carrying on of retail pharmacy businesses by the persons carrying on those businesses (“pharmacy owners”) are amended so that its premises standards are no longer to be set in rules. In addition, the illustrative list of the content of its premises standards is revised, and now indicates that the standards may relate to matters such as the working environment at registered pharmacies and associated premises, and the patient and public experience at registered premises (articles 6, 7, 19(1) to (4), 20 and 22). The GPhC is now also required to consult the Welsh Ministers, the Scottish Ministers and the Secretary of State for Health on all their statutory standards before setting them (article 18). The PSNI is given new powers to set premises standards, worded in essentially the same terms as the equivalent powers of the GPhC (article 13), and some obsolete provisions relating to premises requirements for Northern Ireland are removed (article 8).

Enforcement of premises standards in Great Britain may be by improvement notices served by the GPhC, but unlike breaches of other improvement notices, breaches of improvement notices served in relation to breaches of premises standards are not to lead to criminal sanctions. Instead, the Registrar of the GPhC is given powers to refer non-compliance to the GPhC’s Fitness to Practise Committee (FTPC) (article 23).

The sanctions regime that the FTPC and the PSNI’s Statutory Committee (SC) operate in relation to pharmacy owners is altered in a number of respects. Firstly, the procedure in section 80 of the Medicines Act 1968 (which enables the FTPC and the SC to remove entries from the premises part of the GPhC’s register or from the PSNI premises register – or to disqualify a pharmacy owner) now applies in relation to breaches of PSNI premises standards as well as to breaches of GPhC premises standards. Secondly, the section 80 procedures are changed so that they apply not just to pharmacy owners that are bodies corporate, but also to pharmacy owners that are partnerships or individual pharmacists. Thirdly, provision is made so that sanctions may only be applied in relation to breaches of premises standards where the FTPC or SC is satisfied that the pharmacy owner is unfit to carry on the relevant business safely and effectively (articles 9, 10, 16 and 26).

If the FTPC or SC does decide to impose sanctions at a final hearing after a finding of impairment is made against a pharmacy owner, those sanctions do not take effect until an appeal is determined or the time for bringing an appeal is passed. Powers are therefore given to the committees to enable them to suspend premises entries in the relevant registers after a finding of impairment, until the matter of an appeal is resolved, where this is in the public interest and subject to safeguards by way of rights of appeal (article 11).

The FTPC is also given powers under the Pharmacy Order 2010, and the SC is given powers under the Pharmacy (Northern Ireland) Order 1976, to suspend some or all of a pharmacy owner’s premises entries in the relevant register where an investigation of the pharmacy owner has commenced but has not reached the stage of a final hearing. These powers are given by way of modification of the powers that the FTPC and SC already have to suspend the entries of individual pharmacists in the relevant registers while an investigation of whether their fitness to practise is impaired is ongoing, where it is in the public interest to do so, with essentially the same safeguards by way of rights of appeal (articles (14, 15 and 25).

The GPhC and the PSNI are given powers to make rules or regulations to provide that, where premises entries in the relevant registers have been suspended under these new interim suspension arrangements, they can treat those entries as still in the relevant register for certain purposes (article 5). The PSNI’s usual procedures for making subordinate legislation are applied to regulations made under Part 4 of the Medicines Act 1968 (article 12).

This Order also deals with some matters relating to the gathering and publication of information by the GPhC.

Firstly, article 7 of the Pharmacy Order 2010, which deals with premises standards, also contains rule making provisions that deal with information gathering from pharmacy owners by the GPhC, and these provisions are modified in a number of respects. For example: rule making under that article becomes optional rather than obligatory; the GPhC is permitted to require pharmacy owners to provide information about cautions as well as criminal convictions, and to require pharmacy

owners to provide specified types of additional information about superintendent pharmacists of bodies corporate; and the GPhC is given greater flexibility in terms of what it may set in rules about the process and timing of gathering information. The improvement notice system in the Pharmacy Order 2010 is also changed so that it can be used to deal with failures by pharmacy owners to meet their obligations under the article 7 rules relating to information gathering (articles 19(5) to (8) and 22).

Secondly, it is made clear that GPhC can publish reports of the inspections and other visits that its inspectors make, and that these reports may include an account of the outcomes of such inspections and visits (article 21).

Thirdly, corrections are made to article 29 of the Pharmacy Order 2010, which erroneously provided for the Registrar General to notify the Registrar of the GPhC of deaths of registered pharmacists and registered pharmacy technicians in Great Britain. The requisite notification should in fact be made in England or Wales by a registrar of births and deaths and in Scotland by a district registrar (articles 17 and 24).

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG. It is also available alongside this instrument on www.legislation.gov.uk.

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