
STATUTORY INSTRUMENTS

2016 No. 372

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

PART 4

Amendments to the Pharmacy Order 2010

Amendment of article 3 of the 2010 Order

17. In article 3 of the 2010 Order⁽¹⁾ (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.

(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

(1) Amended by [S.I. 2011/1043](#) and [2015/806](#) and [968](#).

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(2) (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(3) (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”; and

(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)”.

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

(2) Amended by S.I. 2015/968.

(3) 1998 c. 29.

premises in the Register pursuant to section 74D of the Medicines Act 1968(4) (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(5) (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).”.

(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,”.

(4) Section 74D was inserted by [S.I. 2010/231](#).

(5) Subsection (1) was substituted by [S.I. 2010/231](#).

- (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(6) (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”.