STATUTORY INSTRUMENTS

2016 No. 372

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

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(1) (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) 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(2) (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(3) (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(4) (registration of premises: Northern Ireland).".
 - (4) In sub-paragraph (2)—
 - (a) after "sub-paragraph (1)" insert "or (1A)"; and
 - (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".

⁽²⁾ Substituted by S.R. 2012/308.

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

⁽⁴⁾ Section 75 has been amended by S.I. 2010/231 and is amended by article 8.

- (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(**5**) (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".