STATUTORY INSTRUMENTS

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)

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(**1**).

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:

(**1**) 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(**2**);

"the 1976 Order" means the Pharmacy (Northern Ireland) Order 1976(**3**); and

"the 2010 Order" means the Pharmacy Order 2010(**4**).

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**) 1968 c. 67.
(**3**) S.I. 1976/1213 (N.I. 22).
(**4**) S.I. 2010/231.

(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(**5**) (definition 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(**6**) (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(**7**) (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(**8**), paragraph 8 of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976(**9**) or article 14(4)(b) or 56(**10**)";

(b) omit "of that Order"; and

(**5**) 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.
(**6**) 2010 asp 10.
(**7**) 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.
(**8**) Section 82A is inserted by article 11 of this Order.
(**9**) Schedule 3 was substituted by S.R. 2012/308.
(**10**) Articles 14 and 56 are amended by articles 23 and 25 of this Order respectively.

(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)".

Amendment of section 74B of the 1968 Act

6. In section 74B of the 1968 Act(**11**) (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(**12**) (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(**13**) (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(**14**) (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(**15**) 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(**16**) in connection with the carrying on of the business at or from those premises,

(**11**) Section 74B was inserted by S.I. 2010/231.
(**12**) Section 74B was inserted by S.I. 2010/231.
(**13**) Section 75 has been amended by S.I. 2010/231.
(**14**) Section 80 has been amended by S.I. 2007/289 and 2010/231.
(**15**) Paragraph 5A is inserted by article 13 of this Order.
(**16**) Article 7(1) is substituted by article 19(2) of this Order.

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

(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)"; and

(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(**17**) (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—

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