

*Draft Order in Council laid before Parliament under section 62(9) of the Health Act 1999, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2022 No. 000**

**MEDICINES**

**HEALTH CARE AND**

**ASSOCIATED PROFESSIONS**

The Pharmacy (Responsible Pharmacists,  
Superintendent Pharmacists etc.) Order 2022

Made - - - - 2022

*Coming into force in accordance with article 1*

At the Court at Buckingham Palace, the \*\*\* day of \*\*\*

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) and (2A) and 62(4) and (4A) of, and paragraphs 1, 2, 3, 5 and 6 of Schedule 3 to, the Health Act 1999<sup>(1)</sup>.

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

The period of three months mentioned in paragraph 9(2) of that Schedule expired before a draft of this Order in Council, together with a report about the consultation, was laid before Parliament.

A draft of this Order in Council has been approved by resolution of each House of Parliament in accordance with section 62(9) of the Health Act 1999.

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(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, Schedule 10, paragraph 10, and Schedule 15, Part 2; 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; the Children and Social Work Act 2017 (c. 16) ("the 2017 Act"), section 61, and Schedule 5, paragraph 47(h); and S.I. 2002/253 and 254, 2010/231 and 2012/1916. Section 62 has been amended by: the Health and Social Care Act 2001 (c. 15), section 48; the Health and Social Care (Community Health and Standards) Act 2003 (c. 43) ("the 2003 Act"), Schedule 14, Part 2; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 4; and the 2008 Act, Schedule 8, paragraph 2, and Schedule 10, paragraph 11. Schedule 3 has been amended by: the 2002 Act, sections 26(10) and 35; the 2003 Act, 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, and Schedule 15, Part 2; the 2012 Act, section 211 and Schedule 15, paragraphs 61 and 72(4); the 2017 Act, section 61(1) and (4); and S.I. 2002/253 and 254. See the definition of "the relevant regulatory body" in section 60(2B) of the Health Act 1999, inserted by the 2008 Act, Schedule 8, paragraph 1, which is relevant to the powers being exercised.

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

## PART 1

### General provisions

#### **Citation, commencement and interpretation**

1.—(1) This Order may be cited as the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022.

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

(3) Parts 2 and 3 come 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).

#### **Extent**

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

(2) The extent of the amendments made by article 10 and Schedules 1 and 2 is the same as the extent of the enactments amended.

#### **Transitional and saving provisions**

3.—(1) In connection with the commencement of any provision of Part 2 or 3, or the Schedules, the Privy Council may by order make such transitional 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.

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(2) 1968 c. 67.

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

(4) Before making an order under article 1(3) that commences an amendment of the 1968 Act as it applies in Northern Ireland or an amendment of the Pharmacy (Northern Ireland) Order 1976<sup>(4)</sup>, the Privy Council must obtain the agreement of the Department of Health in Northern Ireland to the making of the order.

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

(6) 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

### Responsible pharmacists and superintendent pharmacists

#### Responsible pharmacists

5.—(1) Section 72A of the 1968 Act<sup>(5)</sup> (the responsible pharmacist) is amended as follows.

(2) Before subsection (1) insert the following subsection—

“(A1) Nothing in this Part is to be taken as requiring there to be a responsible pharmacist in respect of premises at or from which a retail pharmacy business is carried on at a time when no medicinal products (whether they are on a general sale list or not) are being—

- (a) offered or exposed for sale by retail or supply in circumstances corresponding to retail sale at or from the premises, or
- (b) assembled, prepared or dispensed at or from the premises with a view to such sale or supply.”

(3) In subsection (2), for “the Ministers in regulations” substitute “the General Pharmaceutical Council in rules in relation to premises in Great Britain or the Council of the Pharmaceutical Society of Northern Ireland in regulations in relation to premises in Northern Ireland”.

(4) Omit subsections (3) to (5).

(5) For subsections (6) and (7) substitute the following subsections—

“(6) The General Pharmaceutical Council may make further provision in rules in relation to the responsible pharmacist in respect of premises in Great Britain, and the Council of the Pharmaceutical Society of Northern Ireland may make further provision in regulations in relation to the responsible pharmacist in respect of premises in Northern Ireland.

(6A) In making any such provision, the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland must have regard to the principle that the

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(3) 1946 c. 36. Section 1 was amended by the Government of Wales Act 1998 (c. 38), Schedule 12, paragraph 2, and the Government of Wales Act 2006 (c. 32), Schedule 10, paragraphs 1 and 2.

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

(5) Section 72A was inserted by the Health Act 2006 (c. 28), section 30(1), and amended by S.I. 2006/2407.

burdens imposed on businesses by rules or regulations should be the minimum necessary to secure the benefits, considered in general terms, which are expected to result from the rules or regulations.

(7) The rules and regulations mentioned in subsection (6) may (amongst other things)—

- (a) make further provision about the matters mentioned in subsection (1);
- (b) make provision about the responsible pharmacist's absence from the premises.

(7A) If such rules or regulations make provision about the responsible pharmacist's absence from the premises, they must also provide that the retail sale of medicinal products on a general sale list may continue at or from the premises during any period in which the responsible pharmacist is absent from the premises.”.

(6) Omit subsection (8).

### **Superintendent pharmacists**

6.—(1) In section 71 of the 1968 Act(6) (business carried on by body corporate)—

(a) in subsection (1), for paragraph (a) (and the following “and”), substitute the following paragraph—

“(a) that there is a superintendent in relation to the retail pharmacy business in respect of whom the requirements specified in subsection (6) are fulfilled, and”;

(b) in subsection (6)—

(i) after paragraph (a), insert the following paragraph—

“(aa) he is a senior manager of the retail pharmacy business who has the authority to make decisions that affect the running of the retail pharmacy business so far as concerns—

- (i) the retail sale of medicinal products (whether they are on a general sale list or not), and
  - (ii) the supply of such products in circumstances corresponding to retail sale,
- and”;

(ii) in paragraph (b), omit “and stating whether he is a member of the board of that body or not”, and omit “, and” at the end of the paragraph, and

(iii) omit paragraph (c);

(c) before subsection (8), insert the following subsection—

“(7A) For the purposes of subsection (6)(aa), a person is a senior manager of a retail pharmacy business if the person plays a significant role (irrespective of whether other individuals also do so) in—

- (a) the making of decisions about how the whole or a substantial part of its activities are to be managed or organised, or
- (b) the actual managing or organising of the whole or a substantial part of those activities.”;

(d) in subsection (8)—

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(6) Section 71 was substituted by the Health Act 2006 (c. 28), section 28, and then amended by S.I. 2010/231, 2011/2647 and 2019/593.

- (i) for the words from “If a person” to “ceases to do so” substitute “If a person who has been the superintendent in relation to a retail pharmacy business ceases to be the superintendent in relation to the business”, and
  - (ii) for “manage the business” substitute “be the superintendent in relation to the business”; and
  - (e) omit subsection (9).
- (2) After section 72A of the 1968 Act (the responsible pharmacist) insert the following section—

**“The superintendent**

**72AA.** It is the duty of the superintendent in relation to a retail pharmacy business to secure that the business is at all times carried on in ways that ensure its safe and effective running so far as concerns—

- (a) the retail sale of medicinal products (whether they are on a general sale list or not), and
- (b) the supply of such products in circumstances corresponding to retail sale.”

(3) In section 78 of the 1968 Act<sup>(7)</sup> (restrictions on use of titles, descriptions and emblems), in subsection (3)(b), omit the words from “, and that the pharmacist who” to “body corporate”.

**Standards of conduct, ethics and performance**

7.—(1) In article 48 of the Pharmacy Order 2010<sup>(8)</sup> (standards of conduct and performance), after paragraph (1) insert the following paragraphs—

“(1A) The standards set under this article may include standards which relate only to the conduct, ethics and performance expected of registered pharmacists who are—

- (a) responsible pharmacists for the purposes of sections 70 to 72 of the Medicines Act 1968, or
- (b) superintendent pharmacists.

(1B) Where the standards set under this article include standards of the type mentioned in paragraph (1A), the standards may include a description of the professional responsibilities of responsible pharmacists or (as the case may be) superintendent pharmacists.”

(2) In paragraph 1 of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976<sup>(9)</sup> (standards of conduct and performance), after sub-paragraph (1) insert the following sub-paragraphs—

“(1A) The standards set under this paragraph may include standards which relate only to the conduct, ethics and performance expected of registered persons who are—

- (a) responsible pharmacists for the purposes of sections 70 to 72 of the Medicines Act 1968, or
- (b) superintendent pharmacists for the purposes of section 71 of that Act.

(1B) Where the standards set under this paragraph include standards of the type mentioned in sub-paragraph (1A), the standards may include a description of the professional responsibilities of responsible pharmacists or (as the case may be) superintendent pharmacists.”

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(7) Section 78 was amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1(12), paragraph 1, the Health Act 2006 (c. 28), section 27, and S.I. 2010/231 and 2019/593.

(8) S.I. 2010/231.

(9) S.I. 1976/1213 (N.I. 22). Schedule 3 was substituted by the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012 (S.R. 2012/308) and has been amended by the Data Protection Act 2018 (c. 12), Schedule 19, paragraph 17, and by S.I. 2015/806.