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.

DRAFT STATUTORY INSTRUMENTS

2022 No. 000

MEDICINES
HEALTH CARE AND
ASSOCIATED PROFESSIONS

The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) 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(e), 2, 3 and 6 of Schedule 3 to, the Health Act 1999(**1**).

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.

(**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 (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) 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 paragraphs (2) and (3), this Order extends to England, Wales, Scotland and Northern Ireland.

(2) Article 10(1) extends to England, Wales and Scotland only.

(3) Article 10(2) extends to Northern Ireland only.

Transitional and saving provisions

3.—(1) In connection with the commencement of any provision of Part 2 or 3, 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.

(**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(**3**) (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 article 10(2), 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

Amendment of the Medicines Act 1968

Amendment of section 67A of the 1968 Act

5.—(1) Section 67A of the 1968 Act(**4**) (defence to offence of contravening section 63(a) or (b): product not sold or supplied) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

"(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;".

(3) In subsection (3), for paragraph (a) substitute—

"(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;".

Amendment of section 67B of the 1968 Act

6.—(1) Section 67B of the 1968 Act(**5**) (defence to offence of contravening section 63(a) or (b): product sold or supplied) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

"(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;".

(**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**) Section 67A was inserted by S.I. 2018/181.
(**5**) Section 67B was inserted by S.I. 2018/181.

(3) In subsection (4), in paragraph (c), after "retail pharmacy business" insert ", or the relevant pharmacy service,".

(4) In subsection (6), in paragraph (b), after "retail pharmacy business" insert ", or the relevant pharmacy service,".

Amendment of section 67C of the 1968 Act

7.—(1) Section 67C of the 1968 Act(**6**) (defence to offence of contravening section 64) is amended as follows.

(2) In subsection (2), for paragraph (a) substitute—

"(a) the product was dispensed—

(i) at or from a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;".

(3) In subsection (4), in paragraph (c), after "retail pharmacy business" insert ", or the relevant pharmacy service,".

(4) In subsection (6), in paragraph (b), after "retail pharmacy business" insert ", or the relevant pharmacy service,".

Amendment of section 67D of the 1968 Act

8. In section 67D of the 1968 Act(**7**) (defences under sections 67A, 67B and 67C: evidence etc) in subsection (4), after "pharmacy" insert "or a relevant pharmacy service".

New section 67F of the 1968 Act

9.—(1) After section 67E of the 1968 Act(**8**) (sections 67A to 67D: interpretation) insert—

"**67F Sections 67A to 67D: "relevant pharmacy service"**

(1) For the purposes of sections 67A to 67D a pharmacy service is a relevant pharmacy service if conditions A and B are met in respect of it.

(2) Condition A is met in respect of a pharmacy service if—

(a) the service is provided in England by a person in the course of carrying on a regulated activity in respect of which the person is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008(**9**);

(b) the service is provided in Wales—

(i) in the course of the business of a hospital,

(ii) in a prison or youth detention accommodation within the meaning of sections 185 to 187 of the Social Services and Well-being (Wales) Act 2014 (anaw 4) (see section 188 of that Act(**10**)),

(**6**) Section 67C was inserted by S.I. 2018/181.
(**7**) Section 67D was inserted by S.I. 2018/181.
(**8**) Section 67E was inserted by S.I. 2018/181 and amended by S.I. 2019/593.
(**9**) 2008 c. 14.
(**10**) Section 188 has been amended by: the Criminal Justice and Courts Act 2015 (c. 2), Schedule 9, paragraph 32; the Regulation and Inspection of Social Care (Wales) Act 2016 (anaw 2), Schedule 3, Part 1; and the Sentencing Act 2020 (c. 17), Schedule 24, paragraph 32.