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

2025 No. 000

medicines

health care and associated professions

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025

Made - - - - 2025

Coming into force in accordance with article 1(2) to (5)

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At the Court at Buckingham Palace, the day of

Present,

The King’s Most Excellent Majesty in Council

This Order in Council is made in exercise of the powers conferred by sections 60(1)(a), (2)(h) and (2A)(b) and (c) and 62(4) and (4A) of, and paragraphs 1(e), 2, 3 and 6 of Schedule 3 to, the Health Act 1999([[1]](#footnote-2)).

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.

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

PART 1

Introductory Provisions

Citation and commencement

1. —(1) This Order may be cited as the Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025.
   1. This article and the listed provisions come into force on the twenty-eighth day after the day on which this Order is made.
   2. This Order, apart from this article and the listed provisions, comes into force on such days as the Privy Council may by order appoint.
   3. Different days may be appointed under paragraph (3) for different purposes or areas.
   4. In this article, “the listed provisions” means—
      1. articles 2, 3 and 7(1) in so far as it relates to article 7(2) and (4), and article 7(2), (4) and (5);
      2. article 8(1) in so far as it relates to article 8(2), and article 8(2) and (4);
      3. article 12(3), (4), (5), (7) to (10), (12) to (14), and (16)(b), and article 12(1) in so far as it relates to article 12(3), (4), (5), (7) to (10), (12) to (14), and (16)(b); and
      4. article 12(19).

Extent

1. —(1) This Order, apart from articles 9 and 10, extends to England and Wales, Scotland and Northern Ireland.
   1. Articles 9 and 10 extend to England and Wales and Scotland.

Privy Council procedures and legislative procedures

1. —(1) The power vested in the Privy Council to make an order under article 1(3) may be exercised by any two or more members of the Privy Council.
   1. The power vested in the Privy Council to make an order under article 1(3) is exercisable by statutory instrument, and for the purposes of section 1 of the Statutory Instruments Act 1946([[2]](#footnote-3)) (definition of “Statutory Instrument”), that power is to be taken to be conferred by an Act of Parliament.
   2. Any act of the Privy Council under this Order is sufficiently signified by an instrument signed by the Clerk of the Privy Council.
   3. Where an order of the Privy Council under article 1(3) 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—
      1. the fact that the order was duly made; and
      2. the order’s terms.

PART 2

Authorisation by a Pharmacist and, in Great Britain, Supervision by a Pharmacy Technician

Exemption from requirement for manufacturer’s licence or marketing authorisation: authorisation of a pharmacist

1. —(1) The Medicines Act 1968([[3]](#footnote-4)) is amended as follows.
   1. In section 10 (exemptions for pharmacists)([[4]](#footnote-5))—
      1. in subsection (1)—
         1. in the words before paragraph (a), after “pharmacist” insert “or in accordance with subsection (1A)”, and
         2. in the words after paragraph (b), for “done by or under the supervision of a pharmacist” substitute “which is done by or under the supervision of a pharmacist or in accordance with subsection (1A) and”;
      2. after subsection (1) insert—

(1A) Something is done in accordance with this subsection if—

(a) it is done in Great Britain in a registered pharmacy, a hospital, a care home service or a health centre,

(b) it is done—

(i) by a registered pharmacy technician who has the authorisation of a pharmacist to do it, or

(ii) under the supervision of a registered pharmacy technician who has the authorisation of a pharmacist to supervise the doing of it, and

(c) it is done with due regard to patient safety.

(1B) See section 10A for provision about authorisations given for the purposes of subsection (1A)(b)(i) and (ii).;

* + 1. in subsection (3), for “Those restrictions” substitute “The restrictions imposed by regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations”;
    2. in subsection (4), in the words after paragraph (b)—
       1. after “health centre” insert “and is done there”, and
       2. after “pharmacist” insert “or in accordance with subsection (1A)”;
    3. in subsection (7A), after “pharmacist” insert “or registered pharmacy technician”; and
    4. in subsection (7B), after “pharmacist” insert “or registered pharmacy technician”.
  1. After section 10 insert—

10A Authorisation for the purposes of section 10(1A)(b)(i) or (ii)

(1) An authorisation given to a registered pharmacy technician for the purposes of section 10(1A)(b)(i) or (ii)—

(a) may be general or specific,

(b) may be given orally or in writing,

(c) may be given subject to conditions or restrictions, and

(d) may be varied or withdrawn by the pharmacist by whom it is given.

(2) An authorisation given for the purposes of section 10(1A)(b)(i) must state, in relation to anything it authorises a registered pharmacy technician to do, that it authorises the registered pharmacy technician to do it only in a registered pharmacy, hospital, care home service or health centre specified in the authorisation.

(3) An authorisation given for the purposes of section 10(1A)(b)(ii) must state, in relation to anything it authorises the registered pharmacy technician to supervise, that it authorises the registered pharmacy technician to supervise it only if it is done in a registered pharmacy, hospital, care home service or health centre specified in the authorisation.

(4) An authorisation given for the purposes of section 10(1A)(b)(i) may (among other things) authorise a registered pharmacy technician—

(a) to prepare or dispense medicinal products in accordance with prescriptions given after the authorisation is given, or

(b) to procure the preparation or dispensing of medicinal products in accordance with prescriptions given after the authorisation is given.

(5) An authorisation given for the purposes of section 10(1A)(b)(ii) may (among other things) authorise a registered pharmacy technician to supervise—

(a) the preparation or dispensing of medicinal products in accordance with prescriptions given after the authorisation is given, or

(b) the procurement of the preparation or dispensing of medicinal products in accordance with prescriptions given after the authorisation is given.

(6) In giving an authorisation for the purposes of section 10(1A)(b)(i) or (ii), a pharmacist must have due regard to patient safety.

(7) A failure to comply with subsection (6)—

(a) does not affect the validity of the authorisation, but

(b) may constitute misconduct for the purposes of section 80 of this Act (power for relevant disciplinary committee to disqualify and direct removal from register) or article 51(1)(a) of the Pharmacy Order 2010 (impairment of fitness to practise) and the relevant disciplinary committee may deal with any such failure accordingly..

Exemption from the requirement for manufacturer’s licence or marketing authorisation: registered pharmacy technicians at hospital aseptic facilities

1. After regulation 4 of the Human Medicines Regulations 2012([[5]](#footnote-6)) (special provisions for pharmacies etc.) insert—

Special provisions for registered pharmacy technicians at hospital aseptic facilities

**4A.**—(1) The prohibitions in regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) do not apply to anything which is done in Great Britain in a hospital aseptic facility in the course of the provision of a relevant pharmacy service if—

(a) it is done as part of a clinical process;

(b) it is done by or under the supervision of a registered pharmacy technician;

(c) in the case of anything done to a medicinal product prior to the retail sale of the medicinal product or the supply of that product in circumstances corresponding to retail sale, what is done consists of—

(i) preparing or dispensing a medicinal product in pursuance of a prescription for a magistral formula product or an officinal formula product, or

(ii) preparing, assembling or dispensing a medicinal product that has already been lawfully placed on the market in the United Kingdom, or the component medicinal products or medical devices of which have already been so placed,

and is with a view to the retail sale of the medicinal product or the supply of that medicinal product in circumstances corresponding to retail sale;

(d) in a case where sub-paragraph (c)(ii) applies, the composition of the medicinal product is not modified by, nor are its components modified by, the preparation, assembly or dispensing in such a way or to the extent that it is appropriate to treat—

(i) the retail sale of that medicinal product, or

(ii) the supply of that medicinal product in circumstances corresponding to retail sale,

as an occasion on which a new medicinal product is placed on the market in the United Kingdom; and

(e) in the case of the dispensing of a medicinal product in pursuance of a prescription or direction given by an appropriate practitioner, the dispensing is in accordance with that prescription or direction.

(2) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products) does not apply to a medicinal product that, as the result of a process of preparation or assembly that is in accordance with paragraph (1), is no longer supplied in accordance with the terms of any authorisation or registration in force for the product of a type mentioned in regulation 3(15), but only if the medicinal product has been labelled with—

(a) the name of the patient for whom it has been ordered; and

(b) such other information as the person preparing or assembling the medicinal product considers it appropriate to add to the label.

(3) For the purposes of paragraph (1)—

(a) a pharmacy service is a “relevant pharmacy service” if conditions A and B in section 67F of the Medicines Act 1968 (sections 67A to 67D: “relevant pharmacy service”) are met in respect of it; and

(b) a medicinal product (including a component medicinal product) has been lawfully placed on the market in the United Kingdom if—

(i) there is an authorisation or a registration in force for the product of the type mentioned in regulation 3(15), or

(ii) there is no such authorisation or registration in force but it has been supplied to the hospital aseptic facility in accordance with Part 10 (exceptions to requirement for marketing authorisation) or as an investigational medicinal product in accordance with the Clinical Trials Regulations..

Assembly of investigational medicinal products in hospitals and health centres

1. —(1) Regulation 37 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (exemption for hospitals and health centres)([[6]](#footnote-7)) is amended as follows.
   1. In paragraph (2)(a)—
      1. after “carried out”, omit “in”; and
      2. in paragraph (ii), after “of a pharmacist” insert “or, in Great Britain, in accordance with paragraph (3) or (4)”.
   2. After paragraph (2) insert—

(3) Something is done in accordance with this paragraph if it is done in Great Britain in a hospital aseptic facility in the course of the provision of a relevant pharmacy service, and—

(a) it is done as part of a clinical process; and

(b) it is done by or under the supervision of a registered pharmacy technician.

(4) Something is done in accordance with this paragraph if it is done in Great Britian and—

(a) it is done (not relying on paragraph (3))—

(i) by a registered pharmacy technician who has the authorisation of a pharmacist to do it, or

(ii) under the supervision of a registered pharmacy technician who has the authorisation of a pharmacist to supervise the doing of it; and

(b) it is done with due regard to patient safety.

(5) For the purposes of paragraph (3), a pharmacy service is a “relevant pharmacy service” if conditions A and B in section 67F of the Medicines Act 1968 (sections 67A to 67D: “relevant pharmacy service”) are met in respect of it.

(6) An authorisation given to a registered pharmacy technician for the purposes of paragraph (4)(a)(i) or (ii)—

(a) may be general or specific,

(b) may be given orally or in writing,

(c) may be given subject to conditions or restrictions, and

(d) may be varied or withdrawn by the pharmacist by whom it is given.

(7) An authorisation given for the purposes of paragraph (4)(a)(i) must state, in relation to anything it authorises a registered pharmacy technician to do, that it authorises the registered pharmacy technician to do it only in a hospital or health centre specified in the authorisation.

(8) An authorisation given for the purposes of paragraph (4)(a)(ii) must state, in relation to anything it authorises the registered pharmacy technician to supervise, that it authorises the registered pharmacy technician to supervise it only if it is done in a hospital or health centre specified in the authorisation.

(9) In giving an authorisation for the purposes of paragraph (4)(a)(i) or (ii), a pharmacist must have due regard to patient safety.

(10) A failure to comply with paragraph (9)—

(a) does not affect the validity of the authorisation, but

(b) may constitute misconduct for the purposes of section 80 of the Medicines Act 1968 (power for relevant disciplinary committee to disqualify and direct removal from register) or article 51(1)(a) of the Pharmacy Order 2010 (impairment of fitness to practise) and the relevant disciplinary committee may deal with any such failure accordingly..

Name

Clerk of the Privy 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 15, Part 2; the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), sections 209 and 210 and Schedule 15, paragraphs 60 and 72; the Children and Social Work Act 2017 (c. 16) (“the 2017 Act”), section 61 the Health and Care Act 2022 (c. 31) (“the 2022 Act”), section 168(2); and S.I. 2012/1916. Section 62 has been amended by: the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 4; the 2008 Act, Schedule 8, paragraph 2, and Schedule 10, paragraph 11; and the 2022 Act, section 168(3). Schedule 3 has been amended by: the 2002 Act, sections 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 4 to 10, and Schedule 15, Part 2; the 2012 Act, section 211 and Schedule 15, paragraphs 61 ; the 2017 Act, section 61(4); the 2022 Act, section 168(4); and S.I. 2002/254. *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. [↑](#footnote-ref-2)
2. () 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. [↑](#footnote-ref-3)
3. () 1968 c. 67. [↑](#footnote-ref-4)
4. () Amendments have been made to subsections (1), (3) and (4) by S.S.I 2002/162, S.I 2006/2407, 2012/1916, 1971/1445 and 2022/849. [↑](#footnote-ref-5)
5. () S.I. 2012/1916. Regulation 4 has been amended by S.I. 2019/775 and 2024/832. [↑](#footnote-ref-6)
6. () S.I. 2004/1031. There are no amendments to regulation 37. [↑](#footnote-ref-7)