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.

D R A F T S T A T U T O R Y I N S T R U M E N T S

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(**a**).

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.

(2) This article and the listed provisions come into force on the twenty-eighth day after the day on which this Order is made.

(3) This Order, apart from this article and the listed provisions, 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 or areas.

(5) In this article, "the listed provisions" means—

(**a**) 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.

(a) 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);

(b) article 8(1) in so far as it relates to article 8(2), and article 8(2) and (4);

(c) 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

(d) article 12(19).

Extent

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

(2) Articles 9 and 10 extend to England and Wales and Scotland.

Privy Council procedures and legislative procedures

3.—(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.

(2) 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(**a**) (definition of "Statutory Instrument"), that power is to be taken to be conferred by an Act of Parliament.

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

(4) 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—

(a) the fact that the order was duly made; and

(b) 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

4.—(1) The Medicines Act 1968(**b**) is amended as follows.

(2) In section 10 (exemptions for pharmacists)(**c**)—

(a) in subsection (1)—

(i) in the words before paragraph (a), after "pharmacist" insert "or in accordance with subsection (1A)", and

(ii) 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";

(b) after subsection (1) insert—

(**a**) 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.

(**b**) 1968 c. 67.

(**c**) 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.

"(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).";

(c) 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";

(d) in subsection (4), in the words after paragraph (b)—

(i) after "health centre" insert "and is done there", and

(ii) after "pharmacist" insert "or in accordance with subsection (1A)";

(e) in subsection (7A), after "pharmacist" insert "or registered pharmacy technician"; and

(f) in subsection (7B), after "pharmacist" insert "or registered pharmacy technician".

(3) 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

5. After regulation 4 of the Human Medicines Regulations 2012(**a**) (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

(**a**) S.I. 2012/1916. Regulation 4 has been amended by S.I. 2019/775 and 2024/832.

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

6.—(1) Regulation 37 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (exemption for hospitals and health centres)(**a**) is amended as follows.

(2) In paragraph (2)(a)—

(a) after "carried out", omit "in"; and

(b) in paragraph (ii), after "of a pharmacist" insert "or, in Great Britain, in accordance with paragraph (3) or (4)".

(3) 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,

(**a**) S.I. 2004/1031. There are no amendments to regulation 37.

(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.".

Exemptions from prohibition on sale or supply of medicinal products not subject to general sale: two types of authorisation of a pharmacist

7.—(1) The Human Medicines Regulations 2012 are amended in accordance with paragraphs (2) to (4).

(2) In regulation 220 (sale or supply of medicinal products not subject to general sale), in paragraph (2), for sub-paragraph (c) substitute—

"(c) P or, if the transaction is carried out on P's behalf by another person, that other person—

(i) is, or acts under the supervision of, a pharmacist, or

(ii) acts in accordance with regulation 220A or 220B.".

(3) After regulation 220 insert—

"**Authorisations given by pharmacists to registered pharmacy technicians**

220A.—(1) A person acts in accordance with this regulation if what that person does is done with due regard to patient safety, and—

(a) that person is a registered pharmacy technician who has the authorisation of a pharmacist to do it; or

(b) what that person does is done under the supervision of a registered pharmacy technician who has the authorisation of a pharmacist to supervise the doing of it.

(2) An authorisation given for the purposes of paragraph (1)—

(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.

(3) An authorisation given for the purposes of—

(a) paragraph (1)(a) 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 at or from the registered pharmacy specified in the authorisation;

(b) paragraph (1)(b) 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 at or from the registered pharmacy specified in the authorisation.

(4) An authorisation given for the purposes of—

(a) paragraph (1)(a) may (among other things) authorise a registered pharmacy technician to carry out transactions that relate to prescriptions received at the registered pharmacy specified in the authorisation after the authorisation is given;

(b) paragraph (1)(b) may (among other things) authorise a registered pharmacy technician to supervise the carrying out of transactions that relate to prescriptions received at the registered pharmacy specified in the authorisation after the authorisation is given.

(5) In giving an authorisation for the purposes of paragraph (1)(a) or (b), a pharmacist must have due regard to patient safety.

(6) A failure to comply with paragraph (5)—

(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.

(7) This regulation does not apply in relation to Northern Ireland.".

(4) Before regulation 221 insert—

"**Sale or supply of items dispensed by a pharmacist who is absent or treated as absent**

220B.—(1) A person (P1) acts in accordance with this regulation where—

(a) the transaction relates to a medicinal product that has been dispensed by or under the supervision of a pharmacist (P2) and is ready for sale or supply to or for the person for whom it has been dispensed;

(b) P2 authorises P1 to carry out the transaction in question on P2's behalf in P2's absence; and

(c) P1 carries out that transaction on P2's behalf—

(i) in P2's absence, or

(ii) in circumstances where P2 is treated as being absent,

in accordance with any conditions or restrictions that P2 has imposed pursuant to sub-paragraph (b)(ii) or (iii) (and the authorisation has not been withdrawn).

(2) An authorisation given for the purposes of paragraph (1)(b)—

(a) may be given orally or in writing;

(b) may be given subject to conditions or restrictions; and

(c) may be varied or withdrawn by P2.

(3) In giving an authorisation for the purposes of paragraph (1)(b), P2 must have due regard to patient safety.

(4) A failure to comply with paragraph (3)—

(a) does not affect the validity of any 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.

(5) For the purposes of paragraph (1)(c)(ii), P2 is to be treated as being absent from premises that are a registered pharmacy if P2 is at the pharmacy but not available to intervene in, or not in a position to intervene in, the transaction in question.".

(5) Pending the coming into force of paragraph (3), the amendment made by paragraph (2) applies as if the reference to regulation 220A were omitted.

Standards of conduct, ethics and performance related to authorisations

8.—(1) Article 48 of the Pharmacy Order 2010(**a**) (standards of conduct and performance) is amended in accordance with paragraphs (2) and (3).

(2) After paragraph (1B) insert—

"(1C) The standards set under this article may include standards which relate to the conduct, ethics and performance expected of registered pharmacists giving authorisations for the purposes of regulation 220B(1)(b) of the Human Medicines Regulations 2012.

(1D) Where the standards set under this paragraph include standards of the type mentioned in paragraph (1C), the standards may include a description of the professional responsibilities that the registered pharmacists have—

(a) for the documentation of authorisations given orally, as mentioned in regulation 220B(1)(b)(i) of the Human Medicines Regulations 2012; and

(b) as a consequence of the professional accountability that the registered pharmacists retain for any selling or supplying that is done pursuant to the authorisation that they have given, and in particular for ensuring due regard for patient safety.".

(3) After paragraph (1D) insert—

"(1E) The standards set under this article may include standards which relate to the conduct, ethics and performance expected of registered pharmacists giving authorisations for the purposes of—

(a) section 10(1A)(b)(i) or (ii) of the Medicines Act 1968;

(b) regulation 37(4)(a)(i) or (ii) of the Medicines for Human Use (Clinical Trials) Regulations 2004; or

(c) regulation 220A(1)(a) or (b) of the Human Medicines Regulations 2012.

(1F) Where the standards set under this article include standards of the type mentioned in paragraph (1E), the standards may include a description of the professional responsibilities that the registered pharmacists have—

(a) for the documentation of authorisations given orally, as mentioned in section 10A(1)(b) of the Medicines Act 1968, regulation 37(6)(b) of the Medicines for Human Use (Clinical Trials) Regulations 2004 and regulation 220A(2)(b) of the Human Medicines Regulations 2012; and

(b) as a consequence of the professional accountability that the registered pharmacists retain for any preparing, assembling, dispensing, selling or supplying that is done pursuant to the authorisation that they have given, and in particular for ensuring due regard for patient safety.".

(4) In paragraph 1 of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976 (**b**)(standards of conduct and performance), after sub-paragraph (1B) insert—

"(1C) The standards set under this paragraph may include standards which relate to the conduct, ethics and performance expected of registered pharmacists giving authorisations for the purposes of regulation 220B(1)(b) of the Human Medicines Regulations 2012.

(**a**) S.I. 2010/231. Relevant amendments have been made to article 48 by S.I. 2022/849 and 851.

(**b**) S.I. 1976/1213 (N.I.22). Schedule 3 was substituted by S.R. 2012 No. 308 and relevant amendments have been made to it by S.I. 2022/849 and 851.

(1D) Where the standards set under this paragraph include standards of the type mentioned in paragraph (1C), the standards may include a description of the professional responsibilities that the registered pharmacists have—

(a) for the documentation of authorisations given orally, as mentioned in regulation 220B(1)(b)(i) of the Human Medicines Regulations 2012; and

(b) as a consequence of the professional accountability that the registered pharmacists retain for any selling or supplying that is done pursuant to the authorisation that they have given, and in particular for ensuring due regard for patient safety.".

PART 3

Consequential Amendments

Consequential amendments to the Misuse of Drugs (Safe Custody) Regulations 1973

9.—(1) The Misuse of Drugs (Safe Custody) Regulations 1973(**a**) are amended as follows.

(2) In regulation 2 (interpretation)(**b**), in paragraph (1)—

(a) at the appropriate place insert—

""pharmacy technician" means a person registered in Part 2 of the register of pharmacists and pharmacy technicians maintained under article 19(1) and (2) of the Pharmacy Order 2010;"; and

(b) in the definition of "retail dealer" after "pharmacist" insert "or pharmacy technician".

(3) In regulation 3 (which relates to safe custody of controlled drugs at retail pharmacy premises and care homes), in paragraph (4)(a), after "in force" insert "or a pharmacy technician designated by such a pharmacist as a person who may have the controlled drug under their direct personal supervision on the premises".

Consequential amendments to the Misuse of Drugs Regulations 2001

10.—(1) The Misuse of Drugs Regulations 2001(**c**) are amended as follows.

(2) In regulation 2 (interpretation)(**d**) in paragraph (1)—

(a) in the definition of "retail dealer" after "pharmacist" insert "or pharmacy technician"; and

(b) at the appropriate place insert—

""pharmacy technician" means a person registered in Part 2 of the register of pharmacists and pharmacy technicians maintained under article 19(1) and (2) of the Pharmacy Order 2010;".

(3) In regulation 6 (general authority to supply and possess)(**e**), in paragraphs (2), (2A) and (3) for "or pharmacist" substitute ", pharmacist or pharmacy technician".

(4) In regulation 6A (supply of articles for administering or preparing controlled drugs)(**f**), in paragraph (2)(b), after "pharmacist" insert "or pharmacy technician".

(5) In regulation 8 (production and supply of drugs in Schedules 2 and 5)(**g**)—

(**a**) S.I. 1973/798.
(**b**) Regulation 2 has been amended by S.I. 2007/2154 and 2011/2581.
(**c**) S.I. 2001/3998.
(**d**) Relevant amendments have been made to regulation 2 by S.I. 2012/973 and 2023/1345.
(**e**) Relevant amendments have been made to regulation 6 by S.I. 2003/1653, 2429, 2005/271, 2012/973, 2015/891 and 2023/1345.
(**f**) Regulation 6A was inserted by S.I. 2003/1653 and relevant amendments have been made to it by S.I. 2005/271 and 2864 and 2014/2081
(**g**) Relevant amendments have been made to regulation 8 by S.I. 2003/2429, 2005/271, 2007/2154, 2010/231, 1621, 2012/973 and 2015/891.

(a) in paragraph (1)(a), for "or pharmacist," substitute ", pharmacist or pharmacy technician,";

(b) in paragraph (2)(b), after "pharmacist" insert "or pharmacy technician"; and

(c) in paragraph (2), in the numbered sub-paragraph (i), after "pharmacist" insert "or pharmacy technician".

(6) In regulation 9 (production and supply of drugs in Schedules 3 and 4)(**a**)—

(a) in paragraph (1)(a), for "or pharmacist" substitute ", pharmacist or pharmacy technician,";

(b) in paragraph (2)(b), after "pharmacist" insert "or pharmacy technician"; and

(c) in paragraph (3)(i), after "pharmacist" insert "or pharmacy technician".

(7) In regulation 15 (form of prescriptions)(**b**), in paragraph (1B), after "pharmacist" insert "or pharmacy technician".

(8) In regulation 16 (provisions as to supply on prescription)(**c**)—

(a) in paragraph (1A), after "pharmacist" insert "or pharmacy technician"; and

(b) in paragraph (1C), after "pharmacist" insert "or pharmacy technician".

(9) In regulation 19 (record-keeping requirements in respect of drugs in Schedules 1 and 2)(**d**), in paragraph (3)(a), for "or pharmacist" substitute ", pharmacist or pharmacy technician".

(10) In regulation 27 (destruction of controlled drugs)(**e**), in paragraph (6), for "or pharmacist" substitute ", pharmacist or pharmacy technician".

Consequential amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004

11. In regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (interpretation)(**f**), at the appropriate place insert—

> ""registered pharmacy technician" means a person registered in Part 2 of the register of pharmacists and pharmacy technicians maintained under article 19(1) and (2) of the Pharmacy Order 2010;".

Consequential amendments to the Human Medicines Regulations 2012 and transitional provision

12.—(1) The Human Medicines Regulations 2012(**g**) are amended in accordance with paragraphs (2) to (19).

(2) In regulation 8(1) (general interpretation)(**h**), at the appropriate places insert—

> ""magistral formula product" means a medicinal product that is prepared pursuant to a detailed specification for it that has been provided by an appropriate practitioner;";
>
> ""officinal formula product" means a medicinal product that is prepared pursuant to a detailed specification for it that is in an official pharmacopoeia;"; and
>
> ""registered pharmacy technician" has the meaning given in regulation 213(1);".

(**a**) Relevant amendments have been made to regulation 9 by S.I. 2003/2429, 2005/271, 2007/2154, 2010/231, 1621, 2012/973 and 2015/891.
(**b**) Relevant amendments have been made to regulation 15 by S.I. 2005/2864, 2006/1450, 2178, 2015/891 and 2020/468.
(**c**) Relevant amendments have been made to regulation 16 by S.I. 2003/1653, 2006/1450 and 2015/891.
(**d**) Relevant amendments have been made to regulation 19 by S.I. 2007/2154.
(**e**) There have been no relevant amending instruments.
(**f**) Relevant amendments have been made to regulation 2(1) by S.I. 2010/231 and 1621, 2012/1916, 2019/593 as amended by 2019/744 and 2020/1394.
(**g**) S.I. 2012/1916.
(**h**) Relevant amendments have been made to regulation 8(1) by S.I. 2013/1855, 2019/593 (as amended by 2020/1394), 2019/775 and 2024/832.

(3) In regulation 62 (classification of UK marketing authorisation or parallel import licence)(**a**), in paragraph (5), after "a pharmacist" insert "or by a person who acts in accordance with regulation 220A or 220B (or an exemption in Chapter 3 of Part 12)".

(4) In regulation 106 (classification of certificate of registration), in paragraph (2), after "a pharmacist" insert "or by a person who acts in accordance with regulation 220A or 220B (or an exemption in Chapter 3 of Part 12)".

(5) In regulation 131 (classification of traditional herbal registration), in paragraph (2), after "a pharmacist" insert "or by a person who acts in accordance with regulation 220A or 220B (or an exemption in Chapter 3 of Part 12)".

(6) In regulation 167 (supply to fulfil special patient needs)(**b**), in paragraph (2)(b), after "a pharmacist" insert "or, in Great Britain, a registered pharmacy technician".

(7) In regulation 217B (original pack dispensing)(**c**), in paragraph (2), for sub-paragraph (b) substitute—

"(b) in circumstances where—

(i) a pharmacist is carrying out, supervising or authorising (under regulation 220B) the carrying out of the sale or supply and the pharmacist considers, or

(ii) in Great Britian, a registered pharmacy technician is carrying out or supervising the sale or supply, pursuant to an authorisation (under regulation 220A) given by a pharmacist, and the registered pharmacy technician considers,

in the exercise of their professional skill and judgement, that the sale or supply of a different quantity to that ordered on the prescription may mean that the patient does not, or is not able to, follow the medication regimen intended by the prescriber.".

(8) In regulation 217BA (original pack dispensing: Northern Ireland)(**d**), in paragraph (2)(b), for "or supervising" substitute ", supervising or authorising (under regulation 220B) the carrying out of".

(9) In regulation 217C (original pack dispensing: medicinal products containing a relevant substance)(**e**), in paragraph (2)—

(a) for sub-paragraph (a) substitute—

"(a) the sale or supply is—

(i) by or under the supervision of or pursuant to an authorisation (under regulation 220B) given by a pharmacist, or

(ii) in Great Britain, by or under the supervision of a registered pharmacy technician, pursuant to an authorisation (under regulation 220A) given by a pharmacist; and";

(b) in sub-paragraph (b), after "the pharmacist" insert "(in a case to which paragraph (a)(i) applies) or registered pharmacy technician (in a case to which paragraph (a)(ii) applies)".

(10) In regulation 217CA (original pack dispensing: medicinal products containing a relevant substance: Northern Ireland)(**f**), in paragraph (2)(a), before "a pharmacist" insert "or pursuant to an authorisation (under regulation 220B) given by".

(11) In regulation 222A (assembly or part assembly as part of "hub and spoke" dispensing arrangements between different businesses)(**g**), in paragraph (4), after "pharmacist", at each place

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(**a**) The relevant amending instrument is S.I. 2014/1878.
(**b**) Regulation 167 has been amended by S.I. 2017/715 and 2019/775.
(**c**) Inserted by S.I. 2023/1015.
(**d**) Inserted by S.R. 2024 No. 125
(**e**) Inserted by S.I. 2023/1015
(**f**) Inserted by S.R. 2024 No. 125.
(**g**) Inserted by S.I. 2025/758, which comes into force on 1st October 2025.

it occurs (five times), insert "or (where this may be delegated to them) a registered pharmacy technician".

(12) In regulation 248 (exemption for certain collection and delivery arrangements)(**a**), in paragraph (2)(b), after "a pharmacist" insert "or by a person who acts in accordance with regulation 220A or 220B".

(13) In regulation 250 (exceptions to regulation 249)(**b**), in paragraph (3), after "a pharmacist" insert "or by a person who acts in accordance with regulation 220A or 220B (or an exemption in Chapter 3 of Part 12)".

(14) In regulation 255 (offences relating to dealings with medicinal products), in paragraph (1)(c), omit "otherwise than by or under supervision of pharmacist".

(15) In regulation 274 (exemptions from regulation 273), in paragraph (2)(a), after "a pharmacist" insert "or, in Great Britian, a registered pharmacy technician pursuant to an authorisation (under regulation 220A) given by a pharmacist".

(16) In regulation 346(2)(c) (review)(**c**)—

(a) after paragraph (xxviiie) insert—

"(xxviiieza) 220A,"; and

(b) before paragraph (xxviiiea) insert—

"(xxviiiezb) 220B,".

(17) In Schedule 25 (packaging requirements: specific provisions)(**d**), in Part 1 (medicines on prescription), in paragraph 6A, after "pharmacist" at each place it occurs (four times), insert "or (where this may be delegated to them) a registered pharmacy technician".

(18) In Schedule 26 (packaging requirements: special provisions)(**e**), in Part 2 (pharmacy exceptions), in paragraph 10A, after "pharmacist" at each place it occurs (four times), insert "or (where this may be delegated to them) a registered pharmacy technician".

(19) Pending the coming into force of article 7(3)—

(a) the amendments made by paragraphs (3), (4), (5), (12), (13) and (15) apply as if the references to regulation 220A were omitted;

(b) the amendment made by paragraph (7) applies as if the new sub-paragraph (b)(ii) were omitted; and

(c) the amendment made by paragraph (9)(a) applies as if the new sub-paragraph (a)(ii) were omitted.

Name
Clerk of the Privy Council

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes provision enabling pharmacists to authorise others, in particular pharmacy technicians, to perform tasks that would otherwise need to be performed by or under the supervision of pharmacists – and for pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities.

The placing on the market of medicinal products for human use in the United Kingdom is regulated principally by the Human Medicines Regulations 2012, but there are additional

(**a**) There are no relevant amending instruments.
(**b**) There are no relevant amending instruments.
(**c**) There are no relevant amending instruments.
(**d**) Paragraph 6A of Schedule 25 was inserted by S.I. 2025/758, which comes into force on 1st October 2025.
(**e**) Paragraph 10A of Schedule 26 was inserted by S.I. 2025/758, which comes into force on 1st October 2025.

requirements in the Medicines Act 1968 and a separate scheme for investigational medicinal products in the Medicines for Human Use (Clinical Trials) Regulations 2004.

At the end of the medicines supply chain, under section 10 of the Medicines Act 1968, pharmacists are entitled to carry out, or supervise the carrying out of, tasks of preparation, assembly and dispensing of medicinal products without a manufacturing licence, even if this means the product is altered in a way that means it is no longer supplied in accordance with the terms of its product licence, if it has one – provided that what is done is done in a registered pharmacy (most commonly a community pharmacy), a hospital, a health centre or a Scottish care home service. Article 4 of this Order amends the Medicines Act 1968 to allow a pharmacist instead to authorise a pharmacy technician either to carry out these tasks or, with the permission of the pharmacist, to supervise others to carry out these tasks. That authorisation can be given subject to conditions and can be expressed in either specific terms, relating to particular orders for medicinal products, or in general terms, potentially covering prescriptions issued after the authorisation is given. That authorisation can also relate to procuring the performance of these tasks, as well as to the actual performance of them. In giving such an authorisation, the pharmacist must have due regard to patient safety, and failure to do so will not invalidate the permission given but the pharmacist will be liable to disciplinary proceedings. These new arrangements will only apply in Great Britain for the time being because pharmacy technicians are not currently a regulated profession in Northern Ireland.

The Human Medicines Regulations 2012 separately regulate (that is, separately from the regulation of preparation, assembly and dispensing) the carrying out of the final sale or supply of medicinal products. Subject to exceptions (for example, ordinary hospital supply), if the transaction involves a prescription only or a pharmacy medicine, prior to the amendments made by this Order, the transaction has had to take place on registered pharmacy premises and has had to be carried out by or under the supervision of a pharmacist. Going forward, in Great Britain, article 7(1) to (3) enables pharmacists to authorise pharmacy technicians to carry out the transactions that take place at or from registered pharmacy premises, or supervise the carrying out of such transactions, subject to a similar framework to that put in place by the parallel changes to section 10 of the Medicines Act 1968 described above. A relevant amendment has also been made by regulation 7 of the Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025 (S.I. 2025/758). This replaced the historic requirement that sales or supplies must take place "on" registered pharmacy premises with a requirement that they must take place "at or from" such premises.

Additionally, if a prescription only or pharmacy medicine has been dispensed and is ready for sale or supply at or from a registered pharmacy (a "checked and bagged medicine"), a pharmacist will be able to authorise any member of the pharmacy staff to undertake the final supply of that checked and bagged medicine in the pharmacist's absence – or where the pharmacist is treated as being absent because they are unavailable or not in a position to intervene (for example, because they are providing clinical services to a patient). This will apply in Northern Ireland as well as Great Britain (article 7(4)).

As indicated above, final supply in the course of the business of a hospital is handled differently to final supply at or from a registered pharmacy. Article 5 of this Order also allows preparation, assembly and dispensing of a medicinal product in a hospital aseptic facility, prior to its final supply, to be done by or under the supervision of a pharmacy technician rather than a pharmacist – thereby enabling a pharmacy technician rather than a pharmacist to lead such a facility. Final supply will then proceed as before. In enabling this change, it is made clear that the medicines supplied to the hospital aseptic facility for preparation, assembly or dispensing must generally be lawfully on the market in the United Kingdom and must not be modified by the preparation, assembly or dispensing to such an extent that a "new" medicinal product is created by that process (there are exceptions for what are known as magistral or officinal formula products). Again, because pharmacy technicians are not a regulated profession in Northern Ireland, this hospital aseptic facility provision will not apply in Northern Ireland for the time being.

Under the separate scheme for the regulation of clinical trials, hospital and health centre pharmacies and dispensaries are able to assemble investigational medicinal products without the

need for a manufacturing licence – and article 6 provides that the new arrangements for authorisation by pharmacists and supervision by pharmacy technicians will also apply, in a simplified way, to the assembly of investigational medicinal products.

For all of these new arrangements for authorisations, the relevant regulators will be able to set standards of conduct, ethics and performance relating to them and article 8 makes clear that these standards could include descriptions of the professional responsibilities that pharmacists are to have for documenting authorisations given orally and of the professional accountability that the pharmacists who give authorisations retain.

Consequential amendments are made to the Misuse of Drugs (Safe Custody) Regulations 1973 (article 9), the Misuse of Drugs Regulations 2001 (article 10), the Medicines for Human Use (Clinical Trials) Regulations 2004 (article 11) and the Human Medicines Regulations 2012 (article 12).

Commencement of the provisions of this Order is split into two categories. In the first category are the provisions of this Order which come into force 28 days after this Order is made. These are the introductory provisions (articles 1 to 3) and the provisions of this Order which relate to checked and bagged medicines (that is, article 7(4), which inserts regulation 220B into the Human Medicines Regulations 2012, and the other amendments and the transitional provisions which are associated with regulation 220B). In the second category are the rest of the provisions of this Order, which will be commenced separately by one or more Orders of the Privy Council (for which, see articles 1(3) and (4) and 3).

An impact assessment has been produced for this instrument and is available from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. A copy of it is also published alongside this instrument on www.legislation.gov.uk.

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