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

2024 No. 000

MEDICINES

HEALTH CARE AND ASSOCIATED PROFESSIONS

The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2024

Made - - - - 2022

Coming into force in accordance with article 1(3) and (4)

CONTENTS

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) and 62(4) and (4A) of, and paragraphs 1(e), 2, 3 and 6 of Schedule 3 to, the Health Act 1999(**a**).

(**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,

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:

Citation and commencement

1.—(1) This Order may be cited as the Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2024.

(2) This article and articles 2 and 3 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 articles 2 and 3, 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.

Extent

2. This Order extends to England and Wales, Scotland and Northern Ireland.

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) Before making an order under article 1(3) that commences any amendment of the Human Medicines Regulations 2012 as it applies to Northern Ireland, the Privy Council must obtain the agreement of the Department of Health in Northern Ireland to the making of the order.

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

(5) 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—

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.

(**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.

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

(b) the order's terms.

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

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

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

(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—

"(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 pharmacy technician who has the authorisation of a pharmacist to do it, or

(ii) under the supervision of a 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 pharmacy technician"; and

(f) in subsection (7B), after "pharmacist" insert "or 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 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,

(d) 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 pharmacy technician to do, that it authorises the pharmacy

(**a**) Amendments have been made to subsections (1), (3) and (4) by….

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 pharmacy technician to supervise, that it authorises the 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 (amongst other things) authorise a 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 (amongst other things) authorise a 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 or article 51(1)(a) of the Pharmacy Order 2010 and the relevant disciplinary committee may deal with any such failure accordingly.".

Definition of "pharmacy technician"

5. In regulation 8(1) of the Human Medicines Regulations 2012 (general interpretation)(**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(2) of the Pharmacy Order 2010;".

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

6. After regulation 4 of the Human Medicines Regulations 2012 (special provisions for pharmacies etc.) insert—

"**Special provisions for pharmacy technicians at hospital aseptic facilities**

4A.—(1) The prohibitions in regulations 17(1) and 46 do not apply to, or in respect of a medicinal product modified by, anything 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 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—

(**a**) S.I. 2012/1916. Regulation 8(1) has been amended by….

(i) preparing or dispensing a medicinal product in pursuance of a prescription for a magistral formula product (where a medicinal product is prepared pursuant to a detailed specification for it that has been provided by an appropriate practitioner) or an officinal formula medicinal product (where a medicinal product is prepared pursuant to a detailed specification for it that is in an official pharmacopoeia), or

(ii) preparing assembling or dispensing a medicinal product that has already been lawfully placed on the market in the United Kingdom, or its component medicinal products or medical devices 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 or its components has not been modified by the preparation, assembly or dispensing in 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) Where paragraph (3) applies, 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).

(3) This paragraph applies where the medicinal product has been labelled with the name of the patient for whom it has been ordered, together with such other information as the person preparing or assembling the medicinal product considers it appropriate to add to the label.

(4) 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 or as an investigational medicinal product in accordance with the Clinical Trials Regulations.".

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 as follows.

(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 pharmacy technicians

220A.—(1) A person acts in accordance with this regulation if—

(a) that person is a 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 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 pharmacy technician to do, that it authorises the pharmacy technician to do it only at or from the registered pharmacy specified in the authorisation; or

(b) paragraph (1)(b) must state, in relation to anything it authorises the pharmacy technician to supervise, that it authorises the 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 pharmacy technician to carry out transactions that relate to prescriptions received at the registered pharmacy specified in the authorisation after the authorisation is given; or

(b) paragraph (1)(b) may (among other things) authorise a 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 any authorisation, but

(b) may constitute misconduct for the purposes of section 80 of the Medicines Act 1968 or article 51(1)(a) of the Pharmacy Order 2010 and the relevant disciplinary committee may deal with any such failure accordingly.

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

(4) After regulation 220A 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 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, an authorisation that may be given subject to conditions or restrictions; 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).

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

(3) A failure to comply with paragraph (2)—

(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 or article 51(1)(a) of the Pharmacy Order 2010 and the relevant disciplinary committee may deal with any such failure accordingly.

(4) 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) In regulation 346(2)(c) (review)(**a**)—

(a) after paragraph (xxviie) insert—

"(xxviiieza) regulation 220A,"; and

(b) after paragraph (xxviie) insert—

"(xxviiiezb) regulation 220B,".

Exemption from prohibition on sale or supply of medicinal products not subject to general sale: minor amendment relating to supply "at or from" registered pharmacy premises

8. In regulation 220 of the Human Medicines Regulations 2012 (sale or supply of medicinal products not subject to general sale), in paragraph (2)(b), for "on" substitute "at or from".

Consequential amendments to the Misuse of Drugs Regulations 2001

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

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

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

(b) at the appropriate place in the alphabetical order insert—

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

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

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

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

(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

---

(**a**) There are no relevant amending instruments.
(**b**) S.I. 2001/3998, as amended.
(**c**) Regulation 2 has been amended by…
(**d**) Relevant amendments have been made to regulation 6 by…
(**e**) Regulation 6A was inserted by… and relevant amendments have been made to it by…
(**f**) Relevant amendments have been made to regulation 8 by…

(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 (provision 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".

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 requirements in the Medicines Act 1968. At the end of the medicines supply chain, pharmacists are entitled to carry out, or supervise the carrying out, of tasks of preparation, assembly and dispensing of medicinal products, 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. 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 carrying 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 (article 4).

Human Medicines Regulations 2012 also separately regulate (that is, separately from the regulation of preparation, assembly and dispensing) the carrying out of the final sale or supply of

(**a**) Relevant amendments have been made to regulation 9 by…
(**b**) Relevant amendments have been made to regulation 15 by….
(**c**) Relevant amendments have been made to regulation 16 by….
(**d**) Relevant amendments have been made to regulation 19 by….
(**e**) There have been no relevant amending instruments.

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 be carried out by or under the supervision of a pharmacist. The restriction to registered pharmacy premises is changed from "on" to "at or from" such premises (article 8). Going forward, in Great Britain, pharmacists will be able 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 that has been put in place to permit pharmacists to authorise pharmacy technicians to prepare, assemble and dispense medicinal products (article 7(1) to (3)).

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 pharmacist anywhere in the United Kingdom will be able to authorised any member of the pharmacy staff to undertake the final supply of that 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) (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. 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 at extent that a "new" medicinal product is created by that process (there are exceptions for what are known as magistral and 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 (article 6).

Consequential amendments are made to the Human Medicines Regulations 2012 (article 5) and the Misuse of Drugs Regulations 2001 (article 9).

Commencement of the amendments to the Medicines Act 1968, the Misuse of Drugs Regulations 2001 and the Human Medicines Regulations 2012 will be by Orders of the Privy Council (articles 1(3) 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.