Draft Regulations laid before Parliament and the Northern Ireland Assembly under section 47(3) and (6)(c) of the Medicines and Medical Devices Act 2021 (c. 3), for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

DRAFT STATUTORY INSTRUMENTS

2025 No. 000

MEDICINES

The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025

Made - - - -	*2025*
Coming into force-	*1st October 2025*

The Secretary of State in relation to England and Wales and Scotland, and the Department of Health in Northern Ireland and the Secretary of State acting jointly in relation to Northern Ireland, make the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(a), (c), (d), (g), (h), (j), (m) and (n) and (2)(a), (c) and (d) and 43(2) of the Medicines and Medical Devices Act 2021(**a**).

The Secretary of State and the Department of Health in Northern Ireland have carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 2(2) to (4) of that Act, the Secretary of State's and the Department of Health in Northern Ireland's overarching objective in making these Regulations is safeguarding public health, and the Secretary of State and the Department of Health in Northern Ireland have had regard to the matters specified in section 2(3) of that Act and consider that, where these Regulations may have an impact on the safety of human medicines, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(c) of that Act, a draft of this instrument was laid before Parliament and the Northern Ireland Assembly and approved by a resolution of each House of Parliament and the Northern Ireland Assembly.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025.

(2) These Regulations come into force on 1st October 2025.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

(**a**) 2021 c. 3. The powers in section 2(1) of the Medicines and Medical Devices Act 2021, and in the provisions that relate to it, are exercisable by the "appropriate authority". *See* section 2(6) of that Act, which contains the definition of "appropriate authority" that is relevant to the powers being exercised.

Amendments to the Medicines Act 1968

2.—(1) The Medicines Act 1968(**a**) is amended as follows.

(2) In section 10 (exemptions for pharmacists)(**b**), in subsection (1)(b)(i), omit "forming part of the same retail pharmacy business".

(3) Omit section 131 (meaning of "wholesale dealing", "retail sale" and related expressions)(**c**).

Amendments to the Human Medicines Regulations 2012

3. The Human Medicines Regulations 2012(**d**) are amended in accordance with regulations 4 to 12.

Amendments to regulation 3

4.—(1) Regulation 3 (scope of these Regulations: special provisions)(**e**) is amended as follows.

(2) In paragraph (2), after "paragraph (5)" insert ", (5A)".

(3) After paragraph (5) insert—

"(5A) This paragraph applies where a medicinal product is assembled in a registered pharmacy on behalf of a doctor with a view to its supply as part of arrangements of the type mentioned in regulation 222A(1)(b), where—

(a) an order for the supply of that medicinal product to or for the use of a particular patient was submitted by or on behalf of the doctor as part of the provision of NHS pharmaceutical services; and

(b) the condition in paragraph (8) is met.".

(4) In paragraph (10), after "paragraph (11)" insert ", (11A)".

(5) After paragraph (11) insert—

"(11A) This paragraph applies where a medicinal product is the result of a process of assembly to which regulation 17(1) does not apply by virtue of paragraph (5A).".

(6) In paragraph (12)(b), for "or (5)" substitute ", (5) or (5A)".

Amendments to regulation 8

5.—(1) Regulation 8 (general interpretation)(**f**) is amended as follows.

(2) In paragraph (1)—

(a) at the appropriate places insert—

""dispensing content for patients", in relation to an internet service, means content communicated publicly by an internet service provider as part of an internet service (for example, on a website) which is relevant to the dispensing of orders for the supply of medicinal products;";

""general practitioner" means a medical practitioner who is included in the General Practitioner Register kept under section 34C of the Medical Act 1983(**g**);";

(**a**) 1968 c. 67.

(**b**) Amendments have been made to subsection (1) by the Regulation of Care (Scotland) Act 2001 (asp 8), Schedule 3, paragraph 5(a), and by S.I. 1971/1445, 2006/2407, 2012/1916 and 2022/849.

(**c**) Section 131 has been amended by: the National Health Service Reorganisation Act 1973 (c. 32), Schedule 4, paragraph 128(2); the National Health Service (Scotland) Act 1978 (c. 29), Schedule 16, paragraph 30; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraph 44; and S.I. 2012/1916.

(**d**) S.I. 2012/1916.

(**e**) The relevant amending instruments are S.I. 2019/775 (as amended by S.I. 2020/1488) and 2024/832.

(**f**) Regulation 8 has been amended by S.I. 2013/1855 and 2593, 2015/1503 (S.R. 2015/354), 2016/186 (S.R. 2016/407), 190 and 696, 2017/715 (S.R. 2017/241), 2018/199 (S.R. 2018/64), 2019/62 (S.R. 2019/10), 593 (as amended by S.I. 2020/1394), 703, 775 (as amended by S.I. 2020/1488) and 1094, 2020/1125 (S.R. 2020/349), 2021/1452, 2022/352, 2024/374, 832 and 1125 and 2025/87 (not yet in force).

(**g**) 1983 c. 54; section 34C was inserted by S.I. 2010/234.

""internet service" means a service made publicly available by means of the internet, which includes a service made publicly available by means of a combination of the internet and an electronic communications service or electronic communications network (within the meanings given to those expressions in section 32 of the Communications Act 2003(**a**));";

""medicinal products on a general sale list" means medicinal products subject to general sale, as provided for by regulation 5(1)(a) (and related expressions are to be construed accordingly);";

""NHS dispensing practice" means the business as part of which NHS pharmaceutical services are provided by general practitioners;"; and

""NHS pharmaceutical services" means—

(a) in England, pharmaceutical services under Part 7 of the National Health Service Act 2006(**b**);

(b) in Wales, pharmaceutical services under Part 7 of the National Health Service (Wales) Act 2006(**c**);

(c) in Scotland, pharmaceutical services under Part 2 of the National Health Service (Scotland) Act 1978(**d**);

(d) in Northern Ireland, pharmaceutical services under Part 6 of the Health and Personal Social Services (Northern Ireland) Order 1972(**e**);"; and

(b) in the definition of "retail pharmacy business", for "or dentist)" substitute ", any other professional practice which is an NHS dispensing practice or a professional practice carried on by a dentist)".

(3) For paragraph (3) substitute—

"(3) In these Regulations, references to selling by retail, or to retail sale, are references to—

(a) selling a product to a person who buys it otherwise than for a purpose specified in regulation 18(5); or

(b) selling or supplying that is treated as or as part of a retail sale by virtue of regulation 222A(2)(a).".

Amendments to regulation 18

6.—(1) Regulation 18 (wholesale dealing in medicinal products)(**f**) is amended as follows.

(2) In paragraph (4), after "within paragraph (5)" insert "(but this is subject to paragraph (5A))".

(3) After paragraph (5) insert—

"(5A) In these Regulations, references to distributing a product by way of wholesale dealing do not include any sale or supply that is treated by virtue of regulation 222A(2)(a) as or as part of a retail sale.".

Amendment to regulation 220

7. In regulation 220 (sale or supply of medicinal products not subject to general sale), in paragraph (2)(b), for "on premises" substitute "at or from premises".

(**a**) 2003 c. 21; section 32 has been amended by S.I. 2011/1210 and 2020/1419.
(**b**) 2006 c. 41.
(**c**) 2006 c. 42.
(**d**) 1978 c. 29.
(**e**) S.I. 1972/1265 (N.I. 14).
(**f**) Regulation 18 was substituted by S.I. 2013/1855 and has been amended by 2019/775 (as amended by S.I. 2020/1488), 2021/1452 and 2024/832.

Amendments to regulation 221

8.—(1) Regulation 221 (sale or supply of medicinal products subject to general sale) is amended as follows.

(2) In paragraph (1), after "at" insert "or from".

(3) In paragraph (2), after "at" insert "or from".

(4) In paragraph (3)(a), after "the place at" insert "or from".

New regulations to support "hub and spoke" dispensing between different businesses

9. After regulation 222 (sale of medicinal products from automatic machines) insert—

"**Assembly or part-assembly as part of "hub and spoke" dispensing arrangements between different businesses**

222A.—(1) Paragraph (2) applies where—

(a) an order for the sale or supply of a medicinal product to or for the use of a particular patient (P) is submitted to a person acting in the course of a retail pharmacy business or an NHS dispensing practice;

(b) the person carrying on the retail pharmacy business or the NHS dispensing practice (B1) has entered into written arrangements (whether or not legally binding) with a person carrying on a retail pharmacy business (B2) which—

(i) are for the purpose of B2 supporting B1 with regard to the fulfilment of orders submitted as mentioned in sub-paragraph (a) (but must not allow B2 to fulfil the order directly), and

(ii) include (but are not limited to) a comprehensive statement of the responsibilities of B1 and B2 in relation to those orders;

(c) B1 has conspicuously displayed a notice—

(i) at B1's registered pharmacy or premises of B1's NHS dispensing practice, if B1 supplies medicinal products to patients who are present at that pharmacy or those premises, and

(ii) in B1's dispensing content for patients, if B1 sells or supplies medicinal products by means of an internet service,

containing the names and addresses of any parties with whom they have entered into arrangements of the type mentioned in sub-paragraph (b) and a brief statement of the general effect of the arrangements;

(d) the medicinal product is—

(i) assembled or part-assembled in the course of B2's business, and

(ii) sold or supplied by B2 to B1,

as part of the written arrangements of the type mentioned in sub-paragraph (b); and

(e) the activities carried out as mentioned in sub-paragraph (d) are carried out with a view to any of the following taking place at or from premises of B1 (following further assembly in the case of part-assembled products)—

(i) the retail sale of the product by B1 to or for the use of P, or

(ii) the supply of the product in circumstances corresponding to retail sale by B1 to or for the use of P.

(2) For the purposes of these Regulations and the Medicines Act 1968, each sale or supply mentioned in paragraph (1)(d)(ii) by B2—

(a) is treated as or as part of a retail sale; and

(b) is treated as being in accordance with a prescription if—

(i) it is for the purpose of fulfilling an order that is a prescription, and

(ii) the final sale or supply is in accordance with the prescription,

notwithstanding that B2 does not have the prescription.

(3) The definitions of "sell" and "supply" in regulation 213(1) do not apply for the purposes of this regulation.

(4) Where both B1 and B2 are retail pharmacy businesses and a pharmacist may, pursuant to regulation 217B, 217BA or 226A, change an order for the sale or supply of a medicinal product, the final decision as regards whether or not that change is to be made for the sale or supply to or for the use of P is for a pharmacist acting on behalf of B1, even if—

(a) an initial decision, in accordance with which a retail sale was made by B2 to B1, was made by a pharmacist acting on behalf of B2; and

(b) the final decision by the pharmacist acting on behalf of B1 is by way of a confirmation of what the pharmacist acting on behalf of B2 initially decided.

Hub and spoke arrangements: sharing of data between different businesses

222B.—(1) For the purposes of section 8(c) (lawfulness of processing: public interest etc) of, and paragraph 2(2)(a), (c) and (d) of Schedule 1 (special categories of personal data etc) to, the Data Protection Act 2018(**a**), paragraph (2) applies to the processing of any data—

(a) by B1 or B2 (as defined in regulation 222A(1)(b)) which relates to a patient; and

(b) which is necessary for the purposes of—

(i) fulfilling an order submitted as mentioned in regulation 222A(1)(a) under the written arrangements between B1 and B2 of the type mentioned in regulation 222A(1)(b), or

(ii) discharging any related professional obligations to the patient (including obligations relating to the keeping of records).

(2) That processing is—

(a) necessary for the performance of a task carried out in the public interest; and

(b) if the data is personal data concerning health, necessary for the purposes of preventative medicine, medical diagnosis or for the provision of health care or treatment.

(3) Any person (P) who—

(a) is employed or engaged by B1 or B2; and

(b) in the course of being so employed or engaged is required to undertake the processing of data described in paragraph (1),

owes a duty of confidentiality in respect of that data (whether or not they would do so but for this paragraph).

(4) That duty—

(a) is a duty of confidentiality which, if not owed by a health care professional, is owed under an enactment or rule of law for the purposes of section 11(1)(b) of the Data Protection Act 2018(**b**) (special categories of personal data etc: supplementary); and

(b) is such that, if the processing is necessary for the purposes described in paragraph (1)(b), P is able, lawfully, to process that data by virtue of this regulation.

(5) For the purposes of paragraph (1)(b)(ii), a professional obligation to a patient is to be regarded as such notwithstanding that discharging the obligation may—

(**a**) 2018 c. 12. Section 8 and paragraph 2 have both been amended by S.I. 2019/419.
(**b**) Section 11 has been amended by S.I. 2019/419.

(a) also be an obligation that arises in some other way (for example, arising from a term of service that is part of NHS pharmaceutical services); or

(b) be done by a person who is not a health care professional.

(6) Paragraphs (1) and (2) do not apply where, in reliance or purported reliance on arrangements of the type mentioned in regulation 222A(1)(b), a person processes any data which relates to a patient but, in the course of the doing of anything that relates to the fulfilling of the order to which that data relates, there is a breach of—

(a) the requirements to be fulfilled if what is done is to be treated as or as part of a retail sale in accordance with regulation 222A(2)(a); or

(b) a duty of confidentiality owed in respect of the data by a health care professional or under an enactment or rule of law as mentioned in paragraph (4)(a).

(7) Words and expressions used in both—

(a) paragraphs (1) to (6); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraphs 2(2)(a), (c) and (d) of Schedule 1 to, the Data Protection Act 2018,

bear the meanings they bear in those provisions of the Data Protection Act 2018.".

Amendment to regulation 274

10. In regulation 274 (exemptions from regulation 273), in paragraph (2)(b), for "on premises" substitute "at or from premises".

Amendment to Schedule 25

11. In Schedule 25 (packaging requirements: specific provisions), in Part 1 (medicines on prescription), after paragraph 6 insert—

"**6A.** Where a product is to be sold or supplied in accordance with an order submitted as mentioned in regulation 222A(1)(a), for the purposes of—

(a) paragraph 2, B1, as defined in regulation 222A(1)(b), is the person who sells or supplies the product;

(b) paragraph 3, the date is instead the date on which the product is ready for sale or supply to or for the patient for whom it is dispensed; and

(c) paragraphs 4 to 6, the final form of the particulars to be included for the final sale or supply to or for the use of a patient is to be determined by a pharmacist acting on behalf of B1, even if—

(i) the inclusion of the particulars was done by or under the supervision of a pharmacist acting on behalf of B2, as defined in regulation 222A(1)(b), and

(ii) the determination by the pharmacist acting on behalf of B1 is by way of a confirmation of what was done by or under the supervision of a pharmacist acting on behalf of B2.".

Amendments to Schedule 26

12.—(1) Schedule 26 (packaging requirements: special provisions) is amended as follows.

(2) In Part 1 (supply by doctors, dentists, nurses and midwives), after paragraph 4 insert—

"**4A.** Where a product is to be sold or supplied in accordance with an order submitted as mentioned in regulation 222A(1)(a), for the purposes of—

(a) paragraph 2, B1, as defined in regulation 222A(1)(b), is the person who sells or supplies the product; and

(b) paragraph 3, the date is instead the date on which the product is ready for sale or supply to or for the patient for whom it is dispensed.".

(3) In Part 2 (pharmacy exceptions), after paragraph 10 insert—

"**10A.** Where a product is to be sold or supplied in accordance with an order submitted as mentioned in regulation 222A(1)(a), for the purposes of—

(a) paragraph 6, B1, as defined in regulation 222A(1)(b), is the person who sells or supplies the product;

(b) paragraph 7, the date is instead the date on which the product is ready for sale or supply to or for the patient for whom it is dispensed; and

(c) paragraphs 8 to 10, the final form of the particulars to be included for the final sale or supply to or for the use of a patient is to be determined by a pharmacist acting on behalf of B1, even if—

(i) the inclusion of the particulars was done by or under the supervision of a pharmacist acting on behalf of B2, as defined in regulation 222A(1)(b), and

(ii) the determination by the pharmacist acting on behalf of B1 is by way of a confirmation of what was done by or under the supervision of a pharmacist acting on behalf of B2.".

Signed by authority of the Secretary of State for Health and Social Care

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Date

Sealed with the Official Seal of the Department of Health in Northern Ireland [date]

L.S.

Name
A senior officer of the Department of Health in Northern Ireland

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations"), which govern the arrangements throughout the United Kingdom for the licensing, manufacture, marketing, wholesale dealing and the sale and supply of medicines for human use. They also amend the Medicines Act 1968 ("the 1968 Act").

Section 10 of the 1968 Act, amongst other matters, allows for certain activities relating to dispensing of medicines to be done without the need for a manufacturer's licence – most significantly, the assembly and preparation of medicines at hospitals and registered pharmacies, where this is undertaken by or under the supervision of a pharmacist. "Registered pharmacies" are the pharmacy premises of retail pharmacy businesses, and section 10(1)(b)(i) of the 1968 Act has until now prevented such pharmacies assembling medicines on behalf of other registered pharmacies – unless both pharmacies were part of the same retail pharmacy business. Going forward, any registered pharmacy will be able to rely on the section 10 exemption to outsource final assembly, or part-assembly, of medicines to any other registered pharmacy. This has been achieved in part by the removal of the restriction in section 10 (regulation 2(2)).

If final assembly or part-assembly had previously been outsourced, the supply of medicines between different businesses would have been considered wholesale dealing. However, rather than updating the definitions of "wholesale dealing" and "retail sale" in section 131 of the 1968 Act,

these definitions have been removed (regulation 2(3)). As a consequence, by virtue of section 132(1) of the 1968 Act, the definitions of these terms in the 2012 Regulations will apply for the purposes of the 1968 Act. The relevant 2012 Regulations definitions have separately been updated to take account of the new outsourcing arrangements (regulations 5(3) and 6).

Regulation 3 of the 2012 Regulations allows, in terms and amongst other matters, for the preparation and assembly of medicines by doctors at the end of the medicines supply chain to be done without the need for a manufacturer's licence. Going forward, this exemption is amended to allow GP practices that provide NHS pharmaceutical services ("NHS dispensing practices") to outsource assembly, or part-assembly, to registered pharmacies (regulation 4). Alongside this, there are related inclusions of new definitions (regulation 5(2)).

The outsourcing permitted by these amendments to section 10 of the 1968 Act and to regulation 3 of the 2012 Regulations provide the legal platform that enables the operation of what is known as "hub and spoke" dispensing. Hub and spoke dispensing is where one entity (a "spoke") takes in an order for the sale or supply of a medicine and arranges for another entity (a "hub") to assemble or part-assemble the medicine that has been ordered. At that stage, to come within the new framework, the hub must then supply the medicine back to the spoke for the spoke to supply it to or for the use of the patient.

The new regulation 222A of the 2012 Regulations (inserted by regulation 9) establishes that the exchanges of medicines between the hub and the spoke are deemed to be a retail sale – and this is in addition to the actual retail sale or supply that takes place when the spoke supplies a medicine to or for the use of the patient. The hub has to be a registered pharmacy in order to benefit from the new arrangements and the spoke has to be either a registered pharmacy or an NHS dispensing practice. General conditions are set for these arrangements, which include displaying a notice to draw the attention of patients of the spoke to the hub and spoke arrangements. In the case of any pharmacies or dispensing doctors that dispense via an internet service, this notice has to be included in the pharmacy's or the practice's internet presence.

The new regulation 222B of the 2012 Regulations (also inserted by regulation 9) provides for a new statutory information gateway for hub and spoke dispensing in order to support the transfer of personal information between the spoke and the hub that is necessary for the purposes of fulfilling the orders and of discharging any related professional obligations. If the statutory conditions that relate to hub and spoke arrangements, or to the confidentiality obligations in respect of processing personal data, are breached, the new information gateway deeming compliance with the relevant data protection legislation would no longer be available to the business.

Ordinarily, during the dispensing process at the end of the medicines supply chain, details of the name and address of the dispenser of a medicine are included in the dispensing label that is affixed to the medicine prior to final supply. These Regulations provide that it is the spoke's name and address that must be on the dispensing label – and the final decisions relating to the particulars to be included, for example the directions for use for the medicine, are to be taken by the spoke. The date of supply on the dispensing label, however, is to be the date of supply from the hub to the spoke, not the date of the final supply from the spoke to the patient (regulations 11 and 12).

Regulations 220, 221 and 274 of the 2012 Regulations are amended respectively to change references to the sale or supply of products "at" or "on" premises to sale or supply "at or from" premises. These amendments bring the 2012 Regulations into line with the 1968 Act in clarifying that transactions may take place from pharmacy premises, the transaction being completed elsewhere (regulations 7, 8 and 10).

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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