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, for approval by resolution of each House of Parliament and the Northern Ireland Assembly.

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

202x No. 0000

HUMAN MEDICINES

The Human Medicines (Exemptions for Pharmacists) (Amendment) Regulations 202x

Made - - - - 202x

Coming into force in accordance with regulation 1

The Secretary of State in relation to England and Wales and Scotland(**a**), and the Secretary of State and the Department of Health in Northern Ireland acting jointly in relation to Northern Ireland(**b**), in exercise of the powers conferred by sections 2(1)(**c**), 3(1)(a), (c), (d), (g), (j), (n), (2)(a), (c) and (d) of the Medicines and Medical Devices Act 2021(**d**), and after having considered the matters in section 2(2) to (4) of that Act, make the following Regulations.

The Secretary of State and the Minister of Health in Northern Ireland make these Regulations having carried out a public consultation, in accordance with section 45(1) of that Act.

In accordance with section 47(3) and (6)(c) of that Act, a draft of the 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 (Exemptions for Pharmacists) (Amendment) Regulations 202x.

(2) [These Regulations come into force on [date]].

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

Amendments to the Medicines Act 1968

2. The Medicines Act 1968(**e**) is amended in accordance with regulations [3 to 7].

(**a**) Section 2(1) is exercisable by the "appropriate authority", and in relation to England and Wales and Scotland, this means the Secretary of State, as defined in section 2(6)(a) of the Medicines and Medical Devices Act 2021.
(**b**) Section 2(1) is exercisable by the "appropriate authority", and in relation to Northern Ireland, this can mean the Department of Health in Northern Ireland and the Secretary of State acting jointly, as defined in section 2(6)(b)(ii) of the Act.
(**c**) The "law relating to human medicines" is defined in section 9 of the Act.
(**d**) 2021 c. 3.
(**e**) 1968 c. 67.

Amendment to section 10 (exemptions for pharmacists)

3. In section 10(**a**), paragraph (1)(b)(i) omit "forming part of the same retail pharmacy business".

Amendments to section 70 (Business carried on by individual pharmacist or by partners)

4. In section 70(**b**), subsection (3) —

(a) in paragraph (b) omit the final "and";

(b) after paragraph (c) insert —

", and

(d) if orders for the sale or supply of medicinal products are submitted at the premises and, pursuant to regulation 222A or 222B of the 2012 Regulations, part of the processing (including preparation and assembly of those products) may be done at one or more other registered pharmacies, the name and address of each of those pharmacies".

Amendments to section 71 (Business carried on by body corporate)

5. In section 71(**c**), subsection (3) —

(a) in paragraph (b) omit the final "and";

(b) after paragraph (c)insert —

", and

(d) if orders for the sale or supply of medicinal products are submitted at the premises and, pursuant to regulation 222A or 222B of the 2012 Regulations, part of the processing (including preparation and assembly of those products) may be done at one or more other registered pharmacies, the name and address of each of those pharmacies".

Amendments to section 72 (Representative of pharmacist in case of death or disability)

6. In section 72(**d**), subsection (2B)—

(a) in paragraph (b) omit the final "and";

(b) after paragraph (c)insert —

", and

(d) if orders for the sale or supply of medicinal products are submitted at the premises and, pursuant to regulation 222A or 222B of the 2012 Regulations, part of the processing (including preparation and assembly of those products) may be done at one or more other registered pharmacies, the name and address of each of those pharmacies".

Amendment to section 131 (meaning of "wholesale dealing", "retail sale" and related expressions)

7. Omit section 131(**e**).

(**a**) Section 10(1); relevant amending instruments are S.I. 1971/1445, 2001/ 2581, 2006/2407 and 2012/1916.
(**b**) Section 70 has been amended by section 27(1) of the Health Act 2006 (c. 28).
(**c**) Section 71 has been amended by section 28(1) of the Health Act 2006 (c. 28).
(**d**) Section 72 has been amended by section 29 of the Health Act 2006 (c. 28).
(**e**) Section 131(5) was amended by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006, paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978, paragraph 128(2) of Schedule 4 to the National Health Service Reorganisation Act 1973 and SI 2012/1916.

Amendments to the Human Medicines Regulations 2012

8. The Human Medicines Regulations 2012(**a**) are amended in accordance with regulations [9 to 17].

Amendment to regulation 8 (general interpretation)

9. In regulation 8(**b**), paragraph (1) at the appropriate places insert—

""medicinal products on a general sale list" means medicinal products subject to general sale, as provided for by regulation 5(1);";

""NHS GP surgery" means the premises of a registered general practitioner, at or from which NHS pharmaceutical services are provided;";

""NHS pharmaceutical services" means—

(a) in relation to England, pharmaceutical services under Part 7 of the National Health Service Act 2006(**c**),

(b) in relation to Wales, pharmaceutical services under Part 7 of the National Health Service (Wales) Act 2006(**d**),

(c) in relation to Scotland, pharmaceutical services under Part 2 of the National Health Service (Scotland) Act 1978(**e**), and

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

""registered general practitioner", is a registered medical practitioner whose name appears on the register kept under section 34C(**g**) of the Medical Act 1983(**h**);".

Amendment to regulation 18 (wholesale dealing in medicinal products)

10.—(1) In regulation 18(**i**), paragraph (4), after "within paragraph (5)" add "(but this is subject to paragraph (5A))".

(2) 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 as a retail sale of the product concerned.".

Amendment to regulation 220 (sale or supply of medicinal products not subject to general sale)

11. In regulation 220, paragraph 2(b), for "on premises" substitute "at or from premises".

Amendment to regulation 221 (sale or supply of medicinal products subject to general sale)

12. In regulation 221—

(a) in paragraph (1), after "at" insert "or from", and

(b) in paragraph (2), after "at" insert "or from".

(**a**) S.I. 2012/1916.
(**b**) Regulation 8; relevant amending instruments are S.I. 2013/1855 and 2593, 2015/1503, 2019/62, 593 and 775.
(**c**) 2006 c. 41.
(**d**) 2006 c. 42.
(**e**) 1978 c. 29.
(**f**) S.I. 1972/1265 (N.I. 14)
(**g**) Section 34C was amended by S.I. 2010/234.
(**h**) 1983 c. 54.
(**i**) Regulation 18, amended by S.I. 2013/1855 and 2019/775.

New regulations to support dispensing across different legal entities, being registered pharmacies

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

"Certain activities treated as a sale carried out by a person

Assembly and sale or supply with a view to onward sale or supply at another pharmacy

222A.—(1) Paragraph (2) applies [if]—

(a) an order has been made for the sale or supply of a medicinal product to, or for the use of, a particular patient ("the patient").

(b) the product is—

(i) assembled in a registered pharmacy, and

(ii) sold or supplied to a person ("the retailer") in the course of the business in medicinal products carried on at or from that pharmacy or NHS GP surgery.

(c) the activities carried out in sub-paragraph (b) are carried out with a view to either of the following taking place at or from an NHS GP surgery or a registered pharmacy—

(i) the retail sale of the product by the retailer to, or for the use of, the patient;

(ii) the supply of the product in circumstances corresponding to retail sale by the retailer to, or for the use of, the patient.

(2) For the purposes of these Regulations and the Medicines Act 1968, the sale or supply mentioned in paragraph (1)(b)(ii) is treated as a retail sale, unless paragraph (3) applies.

(3) This paragraph applies if the retailer has not entered into arrangements (whether or not legally binding)—

(a) with the person carrying [on] the business in medical products at the registered pharmacy in which the product is assembled; and

(b) with regard to dispensing, in the course of that business, or orders made as mentioned in paragraph (1)(a).

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

Assembly and sale or supply in fulfilment of order submitted at another pharmacy business

222B.—(1) Paragraphs (2) and (3) apply [if]—

(a) an order for the sale or supply of a medicinal product to, or for the use of, a particular patient is submitted to a person acting in the course of a retail pharmacy business or a NHS GP surgery (the "first business");

(b) the person carrying on the first business has entered into arrangements (whether or not legally binding) with a person carrying on a retail pharmacy business ("the second business"), with regard to the fulfilling in the course of the second business of orders submitted as mentioned in paragraph (a);

(c) the product is assembled, and sold or supplied, in the course of the second business and those actions—

(i) fulfil (or are intended to fulfil) the order, and

(ii) are carried out pursuant to those arrangements.

(2) For the purposes of these Regulations and the 1968 Act the sale or supply mentioned in paragraph (1)(c) is treated as—

(a) a sale ("the deemed retail sale") carried out, in the course of the first business, by the person who carries on that business (but this does not prevent it also being a sale or supply by the person carrying on the second business); or

(b) if the first business is an NHS GP surgery, a supply in circumstances corresponding to retail sale ("the deemed retail supply") by the person who carries on that business (but this does not prevent it also being a sale or supply by the person carrying on the second business).

(3) For those purposes the deemed retail sale is taken to be carried out at the premises where—

(a) the order is submitted as mentioned in paragraph 1(a); or

(b) anything else forming part of the dispensing of the medicinal product is done in the course of the first business.

(4) Where a person is treated under paragraph (2)(a) as selling a medicinal product, regulation 220(2)(c) and sections 70 to 72A of the Medicines Act 1968 have effect on the assumption that the person is carrying out the sale of the product only at the times when—

(a) the order is submitted as mentioned in paragraph 1(a); or

(b) anything else that forms part of the dispensing of the medicinal product is done in the course of the first business.".

Amendment to regulation 258 (packaging requirements: specific provisions)

14. In regulation 258, after paragraph (1) insert—

"(1A) (a) If this paragraph applies, paragraph (1) applies subject to the following—

(i) paragraph 2 of schedule 25 does not apply, and

(ii) paragraph 6A does.

(b) This paragraph applies if—

(i) a product is sold or supplied in accordance with an order under regulation 222A, and

(ii) the agreement specifies the name and address of the registered pharmacy that must appear on packaging, and that registered pharmacy is either where the product is assembled or supplied to the patient.

(1B) (a) If this paragraph applies, paragraph (1) applies subject to the following—

(i) paragraph 2 of schedule 25 does not apply, and

(ii) paragraph 6B does.

(b) This paragraph applies if—

(i) a product is sold or supplied in accordance with an order under regulation 222B, and

(ii) the agreement specifies the name and address of the registered pharmacy that must appear on packaging, and that registered pharmacy is either the first or second business.".

Amendment to regulation 274 (exemptions from regulation 273)

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

Amendment to regulation 346 (review)

16.—(1) In regulation 346(**a**)—

(**a**) Regulation 346; relevant amending instruments are S.I. 2014/490 and 2015/903.

(a) in sub-paragraph (2)(c), after paragraph (xxviiie), insert—

"(xxviiieza) 222A and 222B,",

(b) in sub-paragraph (5)(a), after "(c)(i)", substitute "to (xxxii)" with "to (xxviiiea)".

Amendment to Schedule 25 (packaging requirements: specific provisions)

17. In Schedule 25, after paragraph 6 insert—

"PART 1A

Sale or supply involving more than one legal entity

6A. The name and address of the person as determined by arrangements required under regulation 222A.

6B. The name and address of the person as determined by arrangements required under regulation 222B.".

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

Address
Date

Sealed with the Official Seal of the Department of Health on [date].

Name
A senior official 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 human medicines. They also amend the Medicines Act 1968 ("the 1968 Act"), which amongst other things, contains provision about the registration of premises of pharmacy business.

The provisions in these Regulations enable the operation of "hub and spoke" dispensing between retail pharmacy businesses that are part of different legal entities.

Section 10 of the 1968 Act prevented a medicinal product, assembled at a registered pharmacy as part of the dispensing of the product, from being sold or supplied at a different retail pharmacy business. This restriction has been removed (regulation 3).

Sections 70, 71 and 72 of the 1968 Act are amended to introduce a requirement that at any premises where hub and spoke dispensing operates a notice is conspicuously displayed providing the name and address of each other registered pharmacy, involved in supply to the patient (regulations 4, 5 and 6).

Regulation 7 removes section 131 of the 1968 Act. By virtue of section 132(1) of the 1968 Act, definitions within the Human Medicines Regulations 2012 will apply.

Regulation 9 introduces a definition for "NHS GP surgery" to capture NHS GPs that provide NHS pharmaceutical services. This definition is used in new insertions to the HMR that provide for hub and spoke dispensing.

Regulation 18 of the 2012 Regulations is amended so that the movement of a medicine between the hub and the spoke for the purposes of the dispensing model created in new regulation 222A is considered a retail sale, and not wholesale dealing (regulation 10).

Regulations 11, 12 and 15 amend regulations 220, 221 and 274 of the 2012 Regulations respectively to clarify "on premises", to provide that final supply to the patient can start at pharmacy premises and end when the medicinal product is delivered to the patient.

[Regulation 13] inserts into the 2012 Regulations two new substantive provisions: regulation 222A and regulation 222B. Each of the regulations provides for a model whereby hub and spoke dispensing can operate between different legal entities.

Regulation 222A provides for a dispensing model where a prescription is submitted to a registered pharmacy or dispensing doctor (the "spoke"), It includes an obligation that there is an arrangement in place between the hub and the spoke. Regulation 222A establishes a retail sale between the hub to the spoke. (This retail sale is in addition to the final supply of the medicinal products from the spoke to the patient.) It also provides that a hub must be a registered pharmacy, whilst a spoke may be either a registered pharmacy or a dispensing doctor.

Regulation 222B provides a dispensing model where a patient submits a prescription into a retail pharmacy or a dispensing doctor (the "spoke"), who will send the prescription to another pharmacy (the "hub"), where it will be prepared and assembled. The hub will then supply the assembled medicinal product directly to the patient. There must be arrangements in place between the hub and the spoke. Under regulation 222B retail sale is deemed to take place between the spoke and the patient (this is in addition to the retail sale supply that taken places between the hub and patient). Regulation 222B also provides that the hub must be a registered pharmacy, whereas the spoke may be either a registered pharmacy or a dispensing doctor.

Regulation 258 and Schedule 25 are amended to include additional provision for specific packaging requirements when a medicinal product is sold or supplied in accordance with either new regulation 222A or 222B. These new provisions allow the registered pharmacies involved in

the dispensing process to determine between them whose of those parties particulars, namely their name and address, are to appear on the outer packaging of the medicine supplied (regulations 14 and 17).

The review provision in regulation 346 of the 2012 Regulations is amended, to add in the 2012 Regulations provisions inserted by these regulations (regulation 16).

A full impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from…