Draft Regulations laid before the Assembly under section 47(3) and (6)(b) of the Medicines and Medical Devices Act 2021, for approval by a resolution of the Assembly

DRAFT STATUTORY RULES OF NORTHERN IRELAND

2024 No.

MEDICINES

The Human Medicines (Amendment Relating to Original Pack Dispensing) Regulations (Northern Ireland) 2024

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Made - - - - 2024
Coming into operation in accordance with regulation 1(2)

The Department of Health, makes the following Regulations in exercise of the powers conferred by sections 2(1), 3(1)(j), (m), and (n) and 43(2) of the Medicines and Medical Devices Act 2021(**1**).

The Department of Health has 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 Department of Health's overarching objective in making these Regulations is safeguarding public health, the Department of Health has had regard to the matters specified in section 2(3) of that Act and considers 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)(b) of that Act, a draft of these Regulations was laid before and approved by a resolution of the Assembly.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment Relating to Original Pack Dispensing) Regulations (Northern Ireland) 2024.

(2) These Regulations shall come into operation on the day after the day on which they are affirmed by resolution of the Assembly.

(3) These Regulations extend to Northern Ireland.

(**1**) 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.

New regulations 217BA and 217CA of the Human Medicines Regulations 2012

2.—(1) The Human Medicines Regulations 2012(**2**) are amended as follows.

(2) After regulation 217B(**3**) (original pack dispensing) insert—

"**Original pack dispensing: Northern Ireland**

217BA.—(1) Subject to paragraphs (2) to (4) and regulation 217CA, for the purposes of this Part, the sale or supply of a prescription only medicine is in accordance with a prescription (and with the directions contained in the prescription) where—

(a) a different quantity is sold or supplied to that ordered on the prescription in order to allow for the sale or supply of the medicine in its manufacturer's original outer packaging; and

(b) the sale or supply is otherwise in accordance with the prescription.

(2) Paragraph (1) does not apply—

(a) to the sale or supply of a different quantity to that ordered on the prescription in circumstances where the different quantity is more than 10% greater or more than 10% less than the quantity ordered on the prescription; or

(b) in circumstances where a pharmacist is carrying out or supervising the sale or supply and the pharmacist 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 as intended by the prescriber.

(3) Paragraph (2) does not apply to—

(a) a medicine in a form that makes it not practicable to dispense in the exact quantity ordered;

(b) a medicine in a container that has an integral means of application or from which it is not practicable to dispense an exact quantity;

(c) a medicine that cannot be dispensed in the quantity ordered without adversely affecting the medicine.

(4) Paragraphs (1) to (3) do not apply in relation to a supply of a prescription only medicine that is subject to paragraphs 2(1) and (1A) of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997(**4**),

until those Regulations expressly apply paragraphs (1) to (3) to those supplies.".

(3) After regulation 217C (original pack dispensing: medicinal products containing a relevant substance) insert—

"**Original pack dispensing: medicinal products containing a relevant substance: Northern Ireland**

217CA.—(1) Subject to paragraph (2) and for the purposes of this Part, the sale or supply of a prescription only medicine containing a relevant substance is not in accordance with a prescription unless—

(a) it is sold or supplied in its manufacturer's original outer packaging; and

(**2**) S.I. 2012/1916, as amended.
(**3**) Inserted by S.I. 2023/1015.
(**4**) S.R. 1997 No. 381. Paragraphs 2(1) and (1A) of Schedule 2 were substituted and added respectively by S.R. 2005 No. 231.

(b) if the sale or supply is of a quantity that is different to the quantity which has been ordered on the prescription, it is sold or supplied in a quantity which is as close as possible to the quantity in which it has been ordered on the prescription.

(2) Paragraph (1) does not apply where—

(a) the sale or supply is by or under the supervision of a pharmacist; and

(b) the pharmacist is satisfied that—

(i) a risk assessment is in place that refers to the need for the patient to be sold or supplied the medicine containing a relevant substance in different packaging from its manufacturer's original outer packaging (for example in a monitored dosage system); and

(ii) unless the medicine containing a relevant substance is unauthorised (other than by reason of it being an authorised product that has ceased to be so as a result of a process of assembly), processes are in place to ensure the supply to or for the patient of the package leaflet.

(3) In this regulation, "relevant substance" means any of the following—

(a) sodium valproate;

(b) valproic acid;

(c) valproate semisodium.".

Sealed with the Official Seal of the Department of Health on ……..2024.

Name
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 (S.I. 2012/1916) ("HMRs") which govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use. The amendments extend to Northern Ireland only and create new dispensing provisions for prescription only medicines. Regulation 214(1) of the HMRs requires prescription only medicines to be sold or supplied in accordance with a prescription given by an appropriate practitioner, subject to exceptions contained in Chapter 3 (exemptions) of Part 12 (Dealings with medicinal products).

Regulation 2 inserts new regulations 217BA and 217CA into the HMRs. Regulation 217BA(1) and (2)(a) provide that a prescription only medicine is sold or supplied in accordance with a prescription where a medicine is sold or supplied in a quantity of up to 10% more or 10% less than the quantity in which the medicine was originally prescribed, if this would enable the medicine to be dispensed in its original outer packaging, provided the sale or supply is otherwise in accordance with the prescription.

Under regulation 217BA(2)(b), the flexibility to provide a different quantity of a medicine in its original outer packaging does not apply where the medicine is dispensed by a pharmacist and the pharmacist judges that the sale or supply of a different quantity may mean that the patient does not, or is not able to, follow the medication regimen as intended by the prescriber.

Regulation 217BA(3) lists categories of medicine to which regulation 217BA(2) does not apply.

Regulation 217BA(4) contains transitional provisions. Regulation 217BA(4) provides that new regulation 217BA(1) to 217BA(3) will only come into effect in relation to NHS prescriptions that are dispensed by community pharmacies in Northern Ireland when expressly applied by the instruments which contain the relevant NHS terms of service that apply to community pharmacies in that country.

Regulation 217CA(1) provides that, subject to the exception in regulation 217CA(2), medicines containing a relevant substance (sodium valproate, valproic acid or valproate semisodium) that have been prescribed must be sold or supplied in their original outer packaging. In addition, in order to be sold or supplied in accordance with the prescription, they must be sold or supplied in a quantity that has been ordered, or is as close as possible to the quantity ordered, on the prescription.