STATUTORY RULES OF NORTHERN IRELAND

2024 No. 125

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

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

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

(2) After regulation 217B(**2**) (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(**3**),

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

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

(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

(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.".

Commencement Information

I1 Reg. 2 in operation at 4.6.2024, see **reg. 1(2)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment Relating to Original Pack Dispensing) Regulations (Northern Ireland) 2024, Section 2.