

New regulations 217B and 217C of the Human Medicines Regulations 2012

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

(2) After regulation 217A^(b) (requirements for prescriptions to be dispensed in an EEA state) insert—

“Original pack dispensing

217B.—(1) Subject to paragraphs (2) to (4) and regulation 217C, 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—

- (a) in England, paragraph 8(1)(b) of Schedule 4, or paragraph 6(1)(b) of Schedule 7, to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013^(c),
- (b) in Wales, paragraph 9(1)(b) of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020^(d),

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

Original pack dispensing: medicinal products containing a relevant substance

217C.—(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

(a) S.I. 2012/1916.

(b) Inserted by S.I. 2014/490 and amended by S.I. 2019/775.

(c) S.I. 2013/349. To which there are amendments not relevant to these Regulations.

(d) S.I. 2020/1073 (W. 241).

- (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.”.

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

Address Date	<i>Name</i> Minister of State Department of Health and Social Care
-----------------	--

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 England and Wales and Scotland 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 a new regulation 217B into the HMRs. Regulation 217B(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 217B(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 217B(3) lists categories of medicine to which regulation 217B(2) does not apply.

Regulation 217B(4) contains transitional provisions. These provide that new regulations 217B(1) to 217B(3) will only come into effect in relation to NHS prescriptions that are dispensed by community pharmacies in England and Wales when expressly applied by the instruments which contain the relevant NHS terms of service that apply to community pharmacies in those countries.

Regulation 217C(1) provides that, subject to the exception in regulation 217C(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.

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 published alongside these Regulations on www.legislation.gov.uk.

© Crown copyright 2023

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of His Majesty's Stationery Office and King's Printer of Acts of Parliament.

£4.90

<http://www.legislation.gov.uk/id/ukdsi/2023/9780348249446>

ISBN 978-0-34-824944-6



9 780348 249446