Draft Regulations laid before Parliament in accordance with section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2023 No. 000

MEDICINES

The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023

Made - - - - ***

Coming into force in accordance with regulation 1(2)

The Secretary of State 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 Secretary of State 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 Secretary of State's overarching objective in making these Regulations is safeguarding public health, the Secretary of State 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)(a) of that Act, a draft of these Regulations was laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023.

(2) These Regulations come into force on the 28th day after the day on which they are made.

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

(**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". Section 2(6) of that Act contains the definition of "appropriate authority" that is relevant to the powers being exercised.

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

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

(2) After regulation 217A(**3**) (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(**4**),

(b) in Wales, paragraph 9(1)(b) of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(**5**),

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—

(**2**) S.I. 2012/1916.
(**3**) Inserted by S.I. 2014/490 and amended by S.I. 2019/775.
(**4**) S.I. 2013/349. To which there are amendments not relevant to these Regulations.
(**5**) S.I. 2020/1073 (W. 241).

(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.".

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

Name
Minister of State
Department of Health and Social Care

Address
Date

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.