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.