August 2023 (updated October 2023)

Briefing: 025/23: Regulations for Original Pack Dispensing and Sodium Valproate Requirements.

Regulations on Original Pack Dispensing (OPD) and a requirement for sodium valproate and related products to be supplied in their original outer packaging (OP), subject to one exception, have been published – The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023.

Key points:

- The rules requiring pharmacists to dispense all licensed medicines containing valproate in the original outer packaging came into force on 11 October 2023.
- Original pack dispensing rules can be used for private prescriptions from 11 October 2023.
- NHS prescriptions cannot be dispensed using the original pack dispensing rules until changes have been made to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations. Further developments of these changes will be announced on our website in due course.

The table on the next page briefly explains the changes for OPD and Sodium Valproate, followed by a fuller explanation in terms of content and timing.

	POMs	Scope	Exceptions to scope	Reg type	Timing and PLPS regulations
Original Pack Dispensing (OPD)	All POMs, except CDs and sodium valproate +	Up to 10% more or less of the prescribed quantity **may** be sold or supplied from that prescribed, to allow OPD	No OPD if: a) If the prescriber's medicine regimen may not be followed; and b) If a special container (see below for details);	Permissive	Only after additional OPD PLPS regulations for **NHS prescriptions**. 11th October 2023 for private prescriptions.
Sodium Valproate +	Sodium valproate, valproic acid, and valproate semisodium	Sale or supply of any medicine containing a relevant substance **must** be sold or supplied in the OP, subject to an exception	No OP sale or supply if: a) A risk assessment is in place and there is a need for the patient to have the product in another packaging AND there is a process for ensuring authorised medicine's patient information leaflet (PIL) is given	Mandatory (subject to exception)	After the Human Medicines Act amendment comes into force (no additional PLPS regulations required)

OPD

The regulations on OPD provide that a different quantity of the prescription-only medicine (POM) than that ordered on the prescription may be sold or supplied where:

- The quantity is no more than 10%, and no less than 10% of the prescribed quantity; and
- This enables the medicine to be dispensed in its original outer packaging, and
- The sale or supply is otherwise in accordance with the prescription.

As an example, a 30-tablet OP medicine may be dispensed against a prescription for 28, and a 28-tablet OP medicine may be dispensed against a prescription for 30.

If the supervising pharmacist considers, in the exercise of their skill and judgement, that selling or supplying more or less medicine in an OP may mean the patient does not or is not able, to follow the prescriber's intended medication regimen, the exact quantity prescribed must be sold or supplied. For example, a supervising pharmacist may consider that the exact quantity of a prescribed antibiotic should be dispensed.

The OPD provisions have not been extended to the Misuse of Drugs Act and Regulations and therefore may not be applied to Controlled Drugs (CDs), the existing prescription requirements for quantities remain the same for CDs. Additionally, the OPD regulations relate only to POMs. Further clarification will be sought.

Additional OPD regulation

The regulations on OPD also provide that a prescription-only medicine is sold or supplied in accordance with a prescription where a different quantity is sold or supplied to that ordered by the prescription, where a medicine:

- Is in a form that makes it impracticable to dispense the exact quantity (e.g., vials);
- Is in a container that has an integral means of application or from which it is not practicable to dispense an exact quantity (e.g., inhalers);
- Cannot be dispensed in the quantity ordered without adversely affecting the medicine (hygroscopic medicines).

This additional provision relates to the special container and related provisions in the Drug Tariff.

Timing

For private prescriptions, the OPD regulations will come into force in Great Britain as soon as the Human Medicines Amendment Regulations come into force on 11 October 2023. For NHS prescriptions, they will come into force after the Terms of Service (in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (PLPS) expressly applies these OPD amendments.

The PLPS already requires OPD where the quantity prescribed is the same as the quantity of the medicines in an OP with a UK marketing authorisation, subject to certain exceptions.

Sodium Valproate +

Medicines containing sodium valproate, valproic acid or valproate semisodium must be sold or supplied in their original outer packaging. The quantity dispensed must be as close as possible to the quantity ordered on the prescription. This regulation is not subject to a 10% restriction and the original pack must be given subject to one exception. The exception is where a risk assessment has been carried out that indicates a need for the patient to be supplied the medicine in different packaging and processes are in place to ensure the supply to the patient of the package information leaflet (PIL) for the authorised product, the supply need not be in the original outer packaging.

This sodium valproate + regulation is separate and distinct from the regulation on OPD and will come into force as soon as the Human Medicines Amendment Regulations come into force on 11 October 2023.

If you have any queries or require more information, please contact:

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