Canice Ward
Head of Medicines Regulatory Group

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Registered Pharmacies

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Dear Colleague,

Valproate-containing Medicines and Original Pack Dispensing (OPD)

The Human Medicines Regulations 2012 have recently been amended by the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023. This amendment makes two significant changes. Firstly, it requires pharmacists to supply original packs of valproate-containing medicines unless defined exceptional circumstances are present. Secondly, it enables pharmacists to supply up to 10% more than or less than the quantity of medicines prescribed on a prescription (other than those containing valproate) so that an original full pack can be supplied. The legislative amendment **does not** apply in Northern Ireland

Further information and guidance on the change can be found on the Medicines & Healthcare products Regulatory Agency (MHRA) website, here. A joint letter on the change from the Chief Medical Officer and Chief Pharmaceutical Officer may be found here and reference to the MHRA drug safety update here.

Valproate-containing Medicines

The Medicines Regulatory Group (MRG) has received a number of queries relating to the applicability of this change in Northern Ireland. Whilst the legislative amendment does not apply in Northern Ireland the MHRA has recommended that guidance relating to valproate-containing medicines should be considered good practice in Northern Ireland. Pharmacists should consider this guidance and use their professional judgement when making supplies of valproate-containing medicines. It is anticipated that similar changes to the Human Medicines Regulations 2012 will be made in Northern Ireland in due course. Additional guidance on this matter has been produced by the SPPG and is available here.

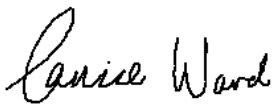
Original Pack Dispensing (OPD)

Currently we interpret dispensing ‘in accordance with a prescription’ to mean pharmacists must supply the exact quantity prescribed. At this time pharmacists in Northern Ireland are not able to avail of the flexibilities to dispense up to 10% more than or less than the quantity of medicines prescribed on a prescription so that an original full pack can be supplied. The intent of the legislative amendment is, in part, to ensure that patients will receive the manufacturer’s Patient Information

Leaflet (PIL). Pharmacists are reminded that it is a professional requirement that a patient information leaflet (PIL) is issued with a medicine at the time of dispensing.[1]

If you have any queries, regarding this matter please contact Aaron McKendry (02890 528628) aaron.mckendry@health-ni.gov.uk or Michelle Keatings (02890 520230) michelle.keatings@health-ni.gov.uk.

Yours sincerely,



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[1] Pharmaceutical Society of Northern Ireland - PROFESSIONAL STANDARDS AND GUIDANCE FOR THE SALE AND SUPPLY OF MEDICINES