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HSS(MD) 51/2023 (Addendum)

FOR ACTION
Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff) and Community Pharmacies
OOHs Medical Managers (for onward distribution to staff)

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Our Ref: HSS(MD) 51/2023 (Addendum)
Date: 5 June 2024

Dear Colleague

ADDENDUM TO HSS(MD) 51/2023 FULL PACK DISPENSING OF VALPROATE-CONTAINING MEDICINES

HSS (MD) 51/2023 was issued on 12 October 2023 to advise that the MHRA guidance on dispensing valproate-containing medicines should be considered by pharmacists in Northern Ireland as good practice. This addendum is an update to advise that amendments to the Human Medicines Regulations 2012 (HMRs) to require manufacturer's original full pack dispensing of valproate-containing medicines came into operation in Northern Ireland on 4 June 2024.

Background

Following a UK wide consultation, the Government has put in place amendments to the Human Medicines Regulations 2012 (HMRs) to:

a) require manufacturer's original full pack dispensing of valproate-containing medicines;

b) enable pharmacists to increase or decrease a prescription by up to 10% (more than or less than) so that they can dispense a manufacturer's original full pack instead of splitting a pack, known as Original Pack Dispensing (OPD).

The MHRA has produced guidance which provides information on the reasons for the change to dispensing of valproate-containing medicines (as above), and outlines what pharmacists need to do differently, including information for patients and the public about valproate. The change came into force in England, Scotland and Wales

on 11 October 2023 and in **Northern Ireland on 4 June 2024**. You can view the guidance **here** - Full pack dispensing of valproate-containing medicines - GOV.UK (www.gov.uk)

This MHRA guidance relates to valproate-containing medicines only. OPD legislation relates to all other medicines and requires further amendments to the Pharmaceutical Services Regulations (NI) 1997 and engagement with community pharmacy colleagues as part of service provision. Once OPD is in operation in Northern Ireland, a further communication will be provided.

Information about valproate-containing medicines

Valproate-containing medicines are used in epilepsy and bipolar disorder. There are known risks associated with valproate-containing medicines, including significant risks to children of mothers who took valproate-containing medicine during pregnancy. Exposure of an unborn baby to valproate during pregnancy is associated with a high risk of congenital malformations (11%) and neurodevelopmental disorders (30–40%), which may lead to permanent disability.

For more information about valproate risks in pregnancy see the MHRA's Valproate use in women and girls page with links to information and guidance for patients and for healthcare professionals on the reproductive risks of valproate and new safety measures introduced to reduce these risks.

Why the rules on dispensing valproate-containing medicines have been changed

The aim of amendments to require manufacturer's original full pack dispensing of valproate-containing medicines is to further decrease the number of babies who are exposed to valproate in pregnancy.

In 2018, a review by the MHRA into the harms of valproate-containing medicines use in pregnancy led to the introduction of the Valproate Pregnancy Prevention Programme as a condition of prescribing and dispensing valproate-containing medicines to women of childbearing potential.

To support these measures, the MHRA asked manufacturers to produce smaller pack sizes of valproate-containing medicines to encourage monthly prescribing and add a pictorial warning about the risks in pregnancy to the labelling of the original packs. Pharmacies were asked to dispense valproate-containing medicines in the original pack where possible and were provided with stickered warnings to add to the outer box if repackaging could not be avoided, due to the prescribed number of medicine doses.

However, some patients and patient groups have continued to raise concerns that warnings are not being provided to patients, and evidence continues to emerge suggesting that women are unaware of the significant risks posed to their unborn baby should they become pregnant while taking valproate-containing medicine.

This new legislative amendment, requiring the supply of valproate-containing medicines in the manufacturer's original full packaging, is a further measure to ensure that patients taking valproate-containing medicines have access to information setting out the risks and need for patients of childbearing potential to fulfil the conditions of the Pregnancy Prevention Programme before taking valproate-containing medicine.

The change in practice will ensure that patients (male and female) are provided with the specific warnings and pictograms on the labelling and a detachable patient card, along with the statutory Patient Information Leaflet and an additional patient booklet, which highlights the risks of taking the medicine while pregnant.

Your role and responsibility as a pharmacist, under the new legislation

From 4 June 2024, the legislative changes that require manufacturer's original full pack dispensing of valproate-containing medicines outlined above, apply to Northern Ireland.

Unless there are exceptional circumstances, valproate-containing medicines must always be dispensed in the manufacturer's original full pack. You must either round up or down so that the patient receives their supply in the manufacturer's original full pack and ensure that they receive an amount that is as close as possible to that prescribed. You must not subsequently re-package any valproate-containing medicine into plain dispensing packaging.

This will ensure that all the safety warnings associated with taking valproate-containing medicine are clearly visible and available to patients. Providing the manufacturer's original full pack with instructions about the safe and effective use of a product is an important patient safety measure.

Exceptional circumstances

The manufacturer's original full pack does not have to be supplied where:

(i) a risk assessment is in place that refers to the need for the patient to be sold or supplied valproate-containing medicines in different packaging from its manufacturer's original full outer packaging (for example, in a monitored dosage system) and

(ii) assuming that the product is authorised, there are processes in place to make sure that the patient receives the Patient Information Leaflet. That is not the case for unauthorised medicines, unless they are only unauthorised as a result of an assembly process.

An example risk assessment is available on the MHRA guidance page.

Further information

No one should stop taking valproate-containing medicines without advice from their healthcare professional.

If patients are concerned about the reproductive risks of valproate-containing medicines, they should discuss this with their doctor, pharmacist, or another healthcare professional.

The new legislation also applies to private prescriptions of valproate-containing medicines.

Reimbursement to community pharmacies

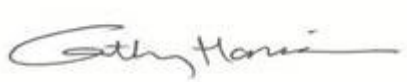
From October 2023 all sodium valproate preparations are now classified as special containers in Northern Ireland. The BSO payment rules in relation to special containers can be found at the link Special-Containers.pdf (hscni.net).

Further information in relation to the reimbursement of valproate-containing medicines prescriptions from October 2023 onwards has been issued to community pharmacies and is available on the BSO website at the following link.

Original Pack Dispensing (OPD)

The legislative changes that will enable pharmacists to increase or decrease a prescription by up to 10% (more than or less than) so that they can dispense a manufacturer's original full pack instead of splitting a pack, known as Original Pack Dispensing (OPD) are transitional. They require further amendments to the Pharmaceutical Services Regulations (NI) 1997 and engagement with community pharmacy as part of service provision. Once OPD is in operation in Northern Ireland, a further communication will be provided.

Yours sincerely



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