# EXPLANATORY MEMORANDUM

## The Human Medicines (Amendment Relating to original Pack Dispensing) Regulations (NI) 2024

## S.R. 2024 No.

## 1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly under section 47(3) and (6)(b) of the Medicines and Medical Devices Act 2021.

1.2 The Statutory Rule is made 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.

1.3 These Regulations are subject to the draft affirmative process for approval by resolution of the Northern Ireland Assembly.

## 2. Purpose of the Regulations

2.1 This Statutory Rule amends the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) ("HMRs"), to introduce original pack dispensing ("OPD") to allow pharmacists in Northern Ireland (including pharmacy staff under the supervision of a pharmacist) the flexibility to dispense up to 10% more or 10% less of a medicine compared to the quantity prescribed, if it means pharmacists can dispense the medicine in its original manufacturer's packaging. This will support increased patient safety by improving patient access to safety information that is included in a medicine's original packaging.

2.2 This Statutory Rule also creates a specific requirement for medicines containing all forms of valproate (valproate is an umbrella term which is used to describe all forms of medicines containing valproate including sodium valproate, valproic acid and valproate semisodium) to always be dispensed in their original manufacturer's packaging (subject to a specific exception), to ensure girls and women receive warnings regarding the risks of taking these medicines when pregnant. However, pharmacists will be able to make an exception to whole-pack dispensing of medicines containing valproate on an individual patient basis, where a risk assessment is in place that refers to the need for different packaging such as a Monitored Dosage System ("MDS") (see sub-section 4.7) and where processes are in place to ensure the supply of Patient Information Leaflets ("PILs"). These Regulations extend to Northern Ireland only.

## 3. Legislative Context

3.1 The HMRs regulate the authorisation, marketing, and pharmacovigilance of medicinal products in Northern Ireland and Great Britain. Regulation 214(1) contained in Part 12 of the HMRs requires that a pharmacist may not sell or supply a prescription only medicine 'except in accordance with a prescription given by an appropriate practitioner'.

3.2 Dispensing 'in accordance with a prescription' is interpreted to mean pharmacists must supply the exact quantity of a medicine prescribed, with a few exceptions.

3.3 The supply to patients of medicines in a manufacturer's original pack without the need to split packs or repackage is termed 'original pack dispensing' - OPD.

3.4 This Statutory Rule inserts new regulation 217BA into the HMRs, to enable OPD to be considered 'in accordance with a prescription' where a pack size is within a 10% deviation from the prescribed amount, if this means an original manufacturer's pack can be dispensed, instead of the pharmacist needing to split a pack. Therefore, the difference of quantity can be up to 10% more or 10% less than the quantity ordered on the prescription. The professional judgement of pharmacists will remain a critical part of the dispensing process for all medicines. The amendment is enabling, and pharmacists will continue to be required to make a clinical decision as to the appropriateness of supplying an original manufacturer's pack rather than the exact quantity prescribed to ensure that the patient's clinical needs are met.

3.5 These amendments to allow OPD of a different quantity within a 10% flexibility will not apply to situations where it is not practicable to dispense the medicine in the exact quantity. In line with current clinical practice these sales and supplies will continue to be considered in 'accordance with a prescription' even if the quantity dispensed is not the quantity stated on the prescription and the deviation from the prescribed amount is more than 10%.

3.6 This Statutory Rule inserts a new regulation 217CA into the HMRs and requires all medicines containing valproate (sodium valproate, valproic acid and, valproate semisodium) to be sold or supplied in their original manufacturer's pack(s). This is because medicines containing valproate, typically used for the treatment of epilepsy and bipolar disorder, can severely harm an unborn child if taken by a girl or woman when pregnant. The original manufacturer's packaging for medicines containing valproate includes warnings on the label, an associated patient card, and the statutory PIL. There is also a patient guide (booklet) available to provide to patients. By always supplying in the manufacturer's original packaging, it will ensure that girls and women always have access to the warnings. Therefore, the medicine will need to be supplied in the nearest number of complete manufacturer's boxes to the quantity prescribed – this will mean the quantity supplied will either round up or down from the quantity prescribed. Sodium valproate and its related medicines were considered as part of the Independent Medicines and Medical Devices Review undertaken by Baroness Cumberlege and are a special case.

3.7 However, pharmacists will be able to make an exception to whole-pack dispensing of medicines containing valproate on an individual patient basis, where a risk assessment is in place that refers to the need for different packaging such as an MDS and where processes are in place to ensure the supply of PILs.

## 4. Policy Background

***What is being done and why?***

4.1 Amendments are being made using powers in Part 2 of the Medicines and Medical Devices Act 2021, which provides powers to make, amongst other things, amendments to the HMRs. Part 2 of the Medicines and Medical Devices Act 2021 requires that when assessing whether regulations would contribute to the objective of safeguarding public health, the appropriate authority must have regard to three factors: the safety of human medicines and that the benefits of any impacts on safety outweigh any risks, the

availability of medicines, and the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to carry out research relating to human medicines, conduct clinical trials and manufacture or supply human medicines.

4.2 The amendments to enable OPD support increased patient safety. If a patient receives the manufacturer's original pack but with some dosage units missing, any tamper evident seal will be broken, so the patient might be concerned either that someone has interfered with the medicine or that the pharmacist has accidentally underfilled their prescription. Additionally, if a patient receives their medicine in a plain dispensing box or bottle, they may get lots of small 'snips' from a blister strip making it difficult to manage their supply, ensure compliance and identify whether they have taken their tablet that day. Additionally, if a patient receives their medicine in a plain dispensing box or bottle, they may not get all the patient information such as the manufacturer's PIL. OPD will also support efficiency, as pharmacy staff spend considerable time splitting boxes, snipping blisters, and repackaging medicines to supply the exact quantity prescribed, this will be reduced if they can supply an original pack more often. The current process also reduces the cost effectiveness of automated dispensing – as, automation cannot 'split and snip' to supply the exact quantity – so for any prescription where this is required, it must be done outside of the automated process.

4.3 These amendments provided are in line with current clinical practice, that supplying a different quantity is not limited to a 10% difference to the quantity prescribed in situations where it is not practicable to dispense the medicine in the exact quantity. This includes for example, the sale or supply of medicines in containers that cannot be split, including inhalers or those with an integral means of application.

4.4 Medicines containing valproate are an effective treatment option for those with epilepsy and bipolar disorder. However, the use of medicines containing valproate was already known to be associated with birth defects when it was first licensed in the 1970s and further evidence has emerged since then about other adverse effects, in particular neurodevelopmental disorders in children where medicines containing valproate are used during pregnancy. The risk of such neurodevelopmental disorders is estimated at 30 to 40% which is in addition to an 11% risk of a congenital abnormality. There are specific warnings and pictograms on the labelling (which are unique) including a patient card, along with the statutory PIL and an additional patient booklet These documents inform patients of the side effects that can occur from using medicines containing valproate and provide details of the risk minimisation measures in place. The amendments to the HMRs specifically aim to support increased patient safety for girls and women, who have been prescribed a medicine containing valproate by ensuring that this group always receive the warnings and information in the manufacturer's packaging.

4.5 As mentioned above in section 3.6, sodium valproate and its associated medicines were considered as part of the Independent Medicines and Medical Devices Review undertaken by Baroness Cumberlege and are a special case.

4.6 The amendment to require pharmacists to dispense medicines containing valproate in original packs offers increased patient safety for girls and women, as it ensures patients will always receive the PIL and other safety warnings on the potential effect the medication can have on unborn babies. The exception to whole-pack dispensing of medicines containing valproate ensures that the measures do not risk cutting across another mitigation to support patients to take their medicines appropriately, such as those who require their medication in an MDS.

4.7 MDSs are packaging which help people take their medicines appropriately, such as containers with compartments marked with the time and the day of the week. MDS is one option pharmacists can consider as a reasonable adjustment as required under the equality law to support people with protected characteristics to take their medicines safely.

***Explanations***

*What did any law do before the changes to be made by this Statutory Rule?*

4.8 Currently dispensing 'in accordance with a prescription' as set out in regulation 214(1) of the HMRs is generally interpreted to mean the dispenser supplying the exact quantity of medicine prescribed, with a few exceptions.

4.9 This means where the quantity prescribed on a prescription is not equal to a (or multiples of) pack size(s), pharmacy staff split manufacturers boxes or other packaging, snipping blisters, and repackaging medicines in plain dispensing packaging (boxes or bottles) in order to dispense the prescribed quantity.

4.10 In the case of medicines containing valproate, pharmacists would need to break down the original manufacturer's packaging, which has specific warnings on the label, an associated patient card, and the statutory PIL. Once these medicines are repackaged in plain dispensing packaging, there is a risk that patients may not receive the complete safety warnings.

*What will it now do?*

4.11 The HMRs are being amended to support increased patient safety and to create efficiencies in the pharmacy sector, in order to create time for pharmacy staff to provide more clinical services.

4.12 New regulation 217B will enable pharmacists to have the flexibility to dispense medicines in the original manufacturer's packaging, where the difference of quantity is up to 10% more or up to 10% less than the quantity ordered on the prescription. Pharmacists will need to apply their clinical judgement if dispensing in an original pack would negatively affect the patient's clinical treatment regimen.

4.13 New regulation 217C will require medicines containing valproate to be dispensed in original manufacturer's packaging, to ensure the unique safety messaging on and within the packaging is always shared with patients. Patients will be supplied with the nearest number of complete manufacturer's boxes to the quantity prescribed - this will mean the quantity supplied will either round up or down from the quantity prescribed. However, pharmacists will be able to make an exception to whole-pack dispensing of medicines containing valproate on an individual patient basis, where a risk assessment is in place that refers to the need for different packaging such as an MDS and where processes are in place to ensure the supply of PILs.

## 5. Consultation

5.1 The Department of Health and Social Care (on behalf of England, Scotland and Wales), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health in Northern Ireland issued a joint public consultation, which was published on GOV.UK and ran for six weeks from 1 November to 13 December 2021. In total, there were 84 responses, 47 of them were from individuals and 37 were from organisations and groups. The consultation sought views on patient safety of OPD and whole-pack dispensing of medicines containing valproate.

5.2 In general, there was very strong support from respondents for the proposals, however, there were a few areas where respondents raised some valuable issues. For example, whilst there was support from many respondents around the 10% flexibility, some respondents felt that it did not go far enough and that 15 or 20% would be more beneficial. However, the flexibility needs to work for patients as well as dispensers and a 15% plus flexibility could significantly alter the prescriber's intended duration of treatment. For example, patients may find themselves falling significantly short of what could reasonably be construed to be a month's supply (or multiples), such as, where a patient needs to take one tablet four times a day a prescription written for a quantity of 112 is a month supply – a flexibility of 15% or above would enable a pack of 100 to be supplied. However, this would only provide the patient with a supply for 25 days rather than 28 days as prescribed. This is too significant a difference from the intention of the prescriber.

5.3 With this all taken into consideration it was agreed at UK national level that 10% is sufficient as it will still capture a significant number of prescriptions (3.7%) and enable more OPD especially for pack sizes of 28 and 30 (and multiplies e.g., 56 and 60), without altering the intent of the prescriber i.e., 'a month's supply'.

5.4 There was overwhelming support for the proposals on medicines containing valproate. However, there were some respondents who felt that exceptions needed to be built in, for example, when patients receive their medication in daily dosages to aid compliance or other means of ensuring compliance. Otherwise, there was a danger that the measure of always dispensing in a manufacturer's original pack for medicines containing valproate so girls and women always get a PIL and therefore protect unborn babies, may cut across other measures to support patient compliance or access to their medicines. These proposals were discussed with the Department of Health in Northern Ireland and all the respective Devolved Administrations (DAs) and found agreement for changes to the proposal. Therefore, the original proposed amendment on medicines containing valproate has been revised. The amendment has been revised to allow pharmacists to make an exception to whole-pack dispensing of medicines containing valproate on an individual patient basis, where a risk assessment is in place that refers to the need for different packaging such as an MDS and where processes are in place to ensure the supply of PILs.

5.5 Most respondents agreed that patient safety would be increased where OPD and whole-pack dispensing of medicines containing valproate are introduced. Many respondents felt that the 10% flexibility was adequate for the introduction of OPD. There was considerable agreement that dispensing original packs would significantly reduce errors and make the medicines easier to trace, which will add to increased patient safety and would also generate incremental time savings for pharmacy staff.

5.6 Respondents largely agreed that in enabling OPD the initial costs to business are outweighed by the potential increase to patient safety and efficiencies gained. From responses, the Government anticipates a marginal reduction in costs to pharmacies as they utilise OPD to maximise efficiency. The UK Government also expects the changes to be cost neutral to other areas of the supply chain, manufacturers, and wholesalers.

5.7 The consultation and consultation response were carried out jointly with the Department of Health in Northern Ireland. The DAs in Scotland and Wales have also been engaged throughout the development of the proposals, consultation response and resulting regulations.

5.8 The consultation response document can be found on the following webpage: Original pack dispensing and supply of medicines containing sodium valproate.

## 6. Guidance

6.1 Guidance accompanying the legislation will be critical for proper implementation and interpretation of the instrument. Guidance for implementation for the amendment for whole-pack dispensing of medicines containing valproate has been provided by the MHRA. Full pack dispensing of valproate-containing medicines - GOV.UK (www.gov.uk). Guidance for the implementation of OPD will also be provided by the Department of Health in Northern Ireland along-side any arrangements made for OPD within Health Service pharmaceutical services including legislative amendments to the Pharmaceutical Services Regulations (NI) 1997.

## 7. Equality impact

7.1 The Department of Health has concluded that the proposed amendments will not have a significant impact on equality of opportunity for any group referred to in section 75 of the Northern Ireland Act 1998 and a full Equality Impact Assessment has not been considered necessary.

## 8. Regulatory impact

8.1 Following the UK wide consultation an Impact Assessment on these enabling legislative changes has been published on the legislation.gov.uk website https://www.legislation.gov.uk/ukia/2023/120/pdfs/ukia_20230120_en.pdf .

## 9. Section 24 of the Northern Ireland Act 1998

9.1 The Department of Health has considered section 24 of the Northern Ireland Act 1998 and is satisfied that these Regulations are not incompatible with any of the Convention rights; are not incompatible with Community law; do not discriminate against a person or class of person on the grounds of religious belief or political opinion; and do not modify an enactment in breach of section 7 of the Northern Ireland Act 1998.

## 10. EU implications

10.1 There are no anticipated EU implications as a result of these amendments.

## 11. Parity or Replicatory Measure

11.1 The provisions included in this Statutory Rule seek to replicate amendments already made in Great Britain through the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023.

## 12. Additional information

12.1 Not applicable