EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT RELATING TO ORIGINAL PACK DISPENSING) (ENGLAND AND WALES AND SCOTLAND) REGULATIONS 2023

2023 No. 1015

1. Introduction

1.1 This explanatory memorandum has been jointly prepared by the Department of Health and Social Care ("DHSC") and the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the DHSC and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument amends the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) ("HMRs"), to introduce original pack dispensing ("OPD") to allow pharmacists (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. A further aim for OPD as part of England's Community Pharmacy Contractual Framework ("CPCF") 5-year deal 2019 to 2024, is to support efficiencies for pharmacies.

2.2 This instrument 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 7.7) and where processes are in place to ensure the supply of Patient Information Leaflets ("PILs").

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is made under the Medicines and Medical Devices Act 2021 ("MMDA") (c.3). This instrument amends the HMRs, which were made under section 2(2) of the European Communities Act 1972. This instrument is subject to the draft affirmative procedure and is being made under powers conferred after 21 June 2017. The procedural and publication requirements of paragraph 13 and 14 of Schedule 8 to the European Union (Withdrawal) Act 2018 therefore do not apply. The statement

required by paragraph 15 of the Schedule 8 to that Act is set out in the Annex to this memorandum.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is Great Britain.

4.2 The territorial application of this instrument is Great Britain.

4.3 A transitional provision is included in this instrument to allow England and Wales the opportunity to arrange how the OPD provision is applied in their respective NHS services. The amendments will come into immediate effect when the instrument comes into force as part of Scotland's NHS service. The requirements for medicines containing valproate to always be dispensed in its original manufacturer's packaging is to apply across Great Britain from when the instrument comes into force.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy, Maria Caulfield, has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 are compatible with the Convention rights".

6. Legislative Context

6.1 The HMRs regulate the authorisation, marketing, and pharmacovigilance of medicinal products in Great Britain. The HMRs were made under section 2(2) of the European Communities Act 1972. 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'.

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

6.3 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.

6.4 This instrument inserts new regulation 217B 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.

6.5 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%.

6.6 This instrument inserts a new regulation 217C 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.

6.7 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.

7. Policy background

What is being done and why?

7.1 Amendments are being made using powers in Part 2 of the MMD, which provides powers to make, amongst other things, amendments to the HMRs. Part 2 of the MMD 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.

7.2 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. Progressing OPD is also part of the CPCF 5-year deal between DHSC, NHSE and Community Pharmacy England, agreement to support efficiencies in the sector.

7.3 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.

7.4 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.

7.5 As mentioned above in section 6.6, 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.

7.6 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.

7.7 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 Act 2010 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 instrument?

7.8 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.

7.9 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.

7.10 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?

7.11 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.

7.12 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.

7.13 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.

7.14 The territorial extent of this statutory instrument is Great Britain.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is not being made under the European Union (Withdrawal) Act 2018, but it does amend regulations (HMRs), which were made under section 2(2) of the European Communities Act 1972. In accordance with the requirements of the European Union (Withdrawal) Act 2018 the Minister has made the relevant statement as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument makes amendments to the HMRs. There are no plans to consolidate the legislation this instrument amends.

10. Consultation outcome

10.1 The Government has engaged widely with stakeholders on the introduction of OPD and whole-pack dispensing of medicines containing valproate, including extensive pre-consultation engagement.

10.2 DHSC, the 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. 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. The Government has determined that this is too significant a difference from the intention of the prescriber.

10.3 With this all taken into consideration, the Government feels 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'.

10.4 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 also discussed with the 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.

10.5 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.

10.6 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 Government also expects the changes to be cost neutral to other areas of the supply chain, manufacturers, and wholesalers.

10.7 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.

10.8 The consultation response document can be found on the following webpage: Original pack dispensing and supply of medicines containing sodium valproate - GOV.UK (www.gov.uk)[1]

11. Guidance

11.1 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 will be provided by the MHRA ahead of it coming into force. Guidance for the implementation of OPD will be provided by the relevant devolved administration when arrangements have been made for OPD within NHS pharmaceutical services.

12. Impact

12.1 The impacts on business, charities or voluntary bodies includes the following:

- costs to patients requiring more repeat prescriptions because of receiving up to 10% less medicine than that prescribed,
- the savings to patients requiring fewer repeat prescriptions because of receiving up to 10% more medicine than that prescribed,
- pharmacies' costs for dispensing more items for repeat prescriptions because of patients having received up to 10% less medicine than that prescribed,
- pharmacies' losses for dispensing less items for repeat prescriptions; because of patients requiring fewer repeat prescriptions because of receiving up to 10% more medicine than that prescribed,
- the savings of medicines because of receiving up to 10% less medicine than that prescribed,
- familiarisation costs – time for pharmacies and patients to understand the changes.

12.2 The impact on the public sector includes the costs of GPs having appointments due to increase or decrease in needing to reissue repeat prescriptions.

12.3 An Impact Assessment has been submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses. The Government foresees that the introduction of OPD and of whole-pack dispensing of medicines containing valproate may create a small burden for pharmacies taking the time to familiarise themselves with the changes and communicate the changes to patients and carers, however, this burden will be outweighed by the increased patient safety and efficiencies gained. With the exception of medicines containing valproate, the instrument does not mandate OPD, and pharmacists therefore do not have to adopt the practice of OPD should they choose not to do so.

[1] https://www.gov.uk/government/consultations/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate

14. Monitoring & review

14.1 DHSC and MHRA will keep the impact of the policy under review. This will be completed via discussions with stakeholders including patient groups and Community Pharmacy England.

14.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 Minister Maria Caulfield has made the following statement:

"It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

15. Contact

15.1 Susan Grieve at DHSC Telephone: 0207 972 2969 or email: susan.grieve@dhsc.gov.uk can be contacted with queries regarding OPD.

15.2 Dr Alison Cave, Chief Safety Officer at the MHRA alison.cave@mhra.gov.uk. To be contacted for queries on whole-pack dispensing of medicines containing valproate.

15.3 Ed Scully, Director of Primary and Community Health Care at DHSC can confirm that this Explanatory Memorandum meets the required standard.

15.4 Maria Caulfield, Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy at DHSC, can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before IP completion day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1) or 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising section 8 or part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Explanations where amending or revoking regulations etc. made under section 2(2) of the European Communities Act 1972

1.1 The Parliamentary Under Secretary of State for Mental Health and Women's Health Strategy, Maria Caulfield has made the following statement regarding regulations made under the European Communities Act 1972:

"In my opinion there are good reasons for the Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 to amend the HMRs. This is because the amendments support increased patient safety and create efficiencies in the pharmacy sector, in order to create time for pharmacy staff to provide more clinical services. Furthermore, the specific requirement that medicines containing valproate are always dispensed in the original manufacturer's packaging, with an exception in very specific circumstances, will ensure that girls and women receive the patient information leaflets and other unique safety warnings, which highlight the serious risks of taking the medicine while pregnant."

1.2 Explanations identifying the relevant law before IP completion day and explaining the effect of this instrument on retained EU law are available in section 7 (sub section 7.8 – 7.14) of the main body of this Explanatory Memorandum.