EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2023

2023 No. 437

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 The instrument amends the Human Medicines Regulations 2012 ('the HMRs') to transpose aspects of Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022. This instrument makes technical amendments introducing a change to permit the holder of a licence to be established in the UK or the EU; a change to the conditions pursuant to which a wholesale dealer may import medicinal products into Northern Ireland (NI) from Great Britain (GB), and a requirement for the MHRA to maintain a list of products to which the derogations provided in the EU legislation have been applied.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the United Kingdom.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The HMRs make provision for the regulation in the United Kingdom of medicinal products for human use. The HMRs cover the manufacture, import, distribution and sale and supply of these products as well as post-market monitoring and pharmacovigilance. The HMRs were made under section 2(2) of the European Communities Act 1972 ('ECA').

6.2 Regulation 6 of the HMRs defines "licensing authority" to mean either or both of the Secretary of State and the Minister for Health, Social Security and Public Safety in Northern Ireland. The MHRA, as an executive agency of DHSC, carries out, on behalf of the licensing authority, the functions of a competent licensing and enforcement authority in the UK in the area of human medicines.

6.3 The framework for the regulation of human medicines in EU law is set out in various Regulations and Directives, chief among them being Directive 2001/83/ EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Following negotiations between the EU and the UK, the EU introduced changes to their legislation through EU Directive 2022/642.

6.4 Directive 2022/642 amends Directives 2001/20/EC and 2001/83/EC to provide derogations from certain obligations in EU law for some medicinal products made available in the United Kingdom in respect of Northern Ireland.

6.5 The Windsor Framework states that Article 13 of Directive 2001/20/EC and Directive 2001/83/EC apply to the United Kingdom in respect to Northern Ireland, which means that the supply of medicinal products placed on the market in Northern Ireland must be in compliance with those provisions of EU law as transposed into the UK regulatory framework.

6.6 This instrument therefore makes technical amendments to ensure that UK domestic law reflects EU Directive 2022/642.

6.7 This instrument will be made under section 8C of the European Union (Withdrawal) Act 2018 and is subject to the negative procedure.

6.8 Further changes to EU law relating to the regulation of medicines in Northern Ireland have been agreed as part of the Windsor Framework, and there will be further revisions to the Human Medicines Regulations required to implement these changes in due course. These further changes do not affect the need to make the changes to the HMRs introduced in this instrument.

7. Policy background

What is being done and why?

7.1 Directive 2022/642 introduced changes to EU law to mitigate supply issues for medicines in Northern Ireland. These changes have already been implemented and are in operation in the UK. The MHRA has also published guidance on the matters covered by this instrument. This instrument now makes the technical amendments necessary to reflect those changes in UK law, as part of the UK's obligations, to ensure that the HMRs are legislatively compliant with EU law.

7.2 Firstly, this instrument amends regulation 17 of the HMRs to ensure those holding a wholesale dealers' licence are exempt from the requirement in regulation 17(1) of the HMRs to also hold a manufacturer's licence when they import a medicinal product into Northern Ireland, provided that certain conditions relating to quality control, licensing and supply are met.

7.3 Secondly, this instrument amends regulation 49 of the HMRs in order to clarify the position with regard to the location of the holder of a marketing authorisation. Directive 2022/642 regularises the position with regard to marketing authorisations that apply in Northern Ireland, so the holder of the marketing authorisation may be based in Great Britain, as well as Northern Ireland or an EEA State. The amendments ensure that there is a consistent position for holders of all marketing authorisations and parallel import licences issued by the licensing authority under the HMRs.

7.4 Thirdly, this instrument inserts new Regulation 345A into the HMRs to provide a new duty for the licensing authority to publish a list of the medicines to which the derogations in the Directive have been applied.

Explanations

What did any law do before the changes to be made by this instrument?

7.5 EU law relating to human medicines applies in relation to NI under the Windsor Framework. EU law is transposed into UK domestic law in the HMRs. The amendments to EU law contained in Directive 2022/642 also apply in relation to NI under the Windsor Framework, as they amend EU Law that applies there. The HMRs implemented EU directives and set out for the UK the requirements for manufacturing, importing and sale and supply of human medicines.

7.6 The majority of the provisions in Directive 2022/642 are already reflected in domestic law.

Why is it being changed?

7.7 The majority of the content of the Directive is already reflected in domestic law. We are making these changes to be compliant with the Withdrawal Agreement. These three minor amendments are necessary for full compliance with the UK obligations under the Windsor Framework.

What will it now do?

7.8 This instrument will ensure effective ongoing regulation of medicines across the whole of the UK. This instrument makes technical updates to our domestic legislation to comply with the EU Directive and bring it up to date.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made under section 8C of the European Union (Withdrawal) Act 2018. The Minister has made any relevant statements in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 No consolidation is being made to legislation as a result of this instrument.

10. Consultation outcome

10.1 No formal consultation has been undertaken for this instrument, since the instrument makes minor technical changes to reflect EU law and implements in UK legislation policy that is already standard practice through operational guidance.

10.2 The proposed amendments have been shared with the Department of Health in Northern Ireland. The Department is content on the technical updates provided for in this SI.

11. Guidance

11.1 The MHRA has published guidance on the matters covered by this instrument which include the following:

- Guidance on Location of Marketing Authorisation Holder and Qualified Person can be found here: https://www.gov.uk/guidance/guidance-on-mah-and-qppv-location
- Guidance on Supplying Medicines from GB to NI can be found here: https://www.gov.uk/guidance/supplying-authorised-medicines-to-northern-ireland
- Guidance on Importing Medicines to NI can be found here: https://www.gov.uk/guidance/importing-medicines-into-northern-ireland
- A list of products using derogations under EU law can be found here: https://www.gov.uk/government/publications/marketing-authorisations-lists-of-products-using-derogations-under-directive-2022642ec

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because of a low level of impact on industry and businesses in the UK. This instrument makes only technical amendments to implement changes that are already operational and set out in EU law.

13. Regulating small business

13.1 The legislation applies activities that are undertaken by small businesses, but this will not have any impact and therefore no specific action needs to be taken to minimise burden.

14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Catherine Lenihan at the Medicines and Healthcare products Regulatory Agency, email: catherine.lenihan@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Rachel Arrundale, Deputy Director at the Medicines and Healthcare products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Maria Caulfield MP, the Parliamentary Under-Secretary of State for Mental Health and Women's Health Strategy at the Department of Health and Social Care 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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

1.1 The explanations statement has been made in section 7 of the main body of this explanatory memorandum.