EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) (EU EXIT) REGULATIONS 2021

2021 No. 834

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations amend the Human Medicines Regulations 2012 ("the HMRs"), which govern the arrangements throughout the United Kingdom for the manufacture, importation and marketing of medicinal products for human use. The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 ("the 2019 Regulations") made an amendment to regulation 3(15) of the HMRs that was subsequently amended by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 ("the 2020 Regulations"), but regrettably this was ineffective due to a numbering error. These Regulations correct that numbering error to restore the original drafting intention and make consequential amendments to the provisions that contained the error.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument 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 Regulation 3 of the HMRs contains exemptions from the manufacturing and product licensing requirements of the HMRs that relate to the manufacture or assembly of medicines by doctors, dentists, nurses and midwives at the final stage of the medicines supply chain – and related to those exemptions, there are provisions of regulation 3 that deal with the packaging, labelling and leafleting requirements for the products covered by those exemptions. The 2019 Regulations made an amendment to an

interpretation provision in paragraph (15) of regulation 3 that related to the repackaging, labelling and leafleting requirements in the case of products covered by a specified list of types of authorisations. Regrettably, because of a numbering error in the drafting of the amendment, introduced into the 2019 Regulations by the 2020 Regulations, the attempt to add "EU marketing authorisation" to the list of types of authorisations was ineffective.

6.2 As this Instrument will be printed to correct an error in SI 2020/1488 (which amended SI 2019/775, which amended SI 2012/1916) it will be issued free of charge to all known recipients of that Statutory Instrument.

7. Policy background

What is being done and why?

Making corrections to the UK statute book

7.1 This instrument corrects a numbering error in the 2020 Regulations, which were intended to add medicines which had received a marketing authorisation within the EU to the types of authorisation accepted within the interpretation of an authorised medicinal product.

7.2 This amendment, had it been effective would have ensured that at the end of the Implementation Period, the HMRs accurately reflected the regulatory situation across the UK. That is, with respect to Northern Ireland and the Northern Ireland Protocol, that medicines with an EU marketing authorisation would be authorised in Northern Ireland.

7.3 This instrument will provide the necessary updates to the HMRs to ensure that the error is corrected and the full range of medicines available within Northern Ireland are listed within the recognised types of approval for the purposes of Regulation 3.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is made using the powers in section 8C(1) of the European Union (Withdrawal) Act 2018, as it is correcting an error in an amendment that was made in order to implement the Northern Ireland Protocol.

8.2 In accordance with the requirements of EUWA the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 There are no plans to consolidate the legislation amended by this instrument.

10. Consultation Outcome

10.1 No formal consultation has taken place.

10.2 The devolved administrations have been engaged on these changes.

11. Guidance

11.1 The Medicines and Heath products Regulatory Agency (MHRA) and the Northern Ireland Executive (NIE) will ensure that relevant professionals are aware of these changes and the regulatory approach until they are in place.

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 An impact assessment has not been produced for this instrument as no, or no significant, impact on private, public, or voluntary sectors is foreseen.

13. Regulating small business

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

13.2 The MHRA will seek provide guidance to relevant stakeholders. As the change to legislation is technical and intended align working practice with regulations the impact to businesses will be minimal.

14. Monitoring & review

14.1 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Jason Eldridge at the Medicines and Heath products Regulatory Agency email: **Jason.Eldridge@mhra.gov.uk** can be contacted with any queries regarding the instrument.

15.2 Jack Turner at the Medicines and Health products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister of State for Health, Edward Argar, 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

Part 1

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), 9 and 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), 9 and 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), 9 and 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)e, 9 and 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), 9 and 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 exit 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), 9, and	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 sections 10(1), 12 and 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 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after exit 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 exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 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.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Sifting Statement

1.1 The Minister of State for Health, Edward Argar MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Human Medicines (Amendment) (EU Exit) Regulations 2021 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)".

1.2 This is the case because the changes to be made within this instrument are minor technical amendments which are being made to correct a failed amendment in previous legislation. These are not expected to have any significant, impact on private, public or voluntary sectors and will enable continued day to day working under the NIP.

2. Appropriateness statement

2.1 The Minister of State for Health, Edward Argar MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view The Human Medicines (Amendment) (EU Exit) Regulations 2021does no more than is appropriate".

2.2 This is the case because this instrument is necessary to ensure that the statute book continues to function correctly following the end of the Implementation Period.

3. Good reasons

3.1 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

3.2 These reasons are set out in section 7 of the Explanatory Memorandum.

4. Equalities

4.1 The Minister of State for Health, Edward Argar, has made the following statement:

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

4.2 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Minister of State for Health, Edward Argar, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.".

5. Explanations

5.1 The explanations statement has been made in section 2 of the main body of this Explanatory Memorandum.