EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT) (SUPPLY TO NORTHERN IRELAND) REGULATIONS 2021

2021 No. 1452

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.

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

2. Purpose of the instrument

2.1 The instrument deals with matters arising out of and related to, the Northern Ireland Protocol (NIP) and amends the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the HMRs") to introduce a new route for supply of prescription only medicines from Great Britain (GB) into Northern Ireland (NI).

2.2 This supply route relies on Article 5(1) of Directive 2001/83/EC. This measure is aimed at ensuring that the UK Government can continue to support the ongoing supply of medicines to NI where there is no NI licensed alternative medicine available.

2.3 This new supply route will permit certain medicines authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) in GB, meaning they have satisfied the MHRA's stringent requirements for medicine safety, quality and efficacy, to be supplied to NI on the basis of the medicine's authorisation in GB. This route is known as the Northern Ireland MHRA Authorised Route (NIMAR).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument amends legislation made under section 2(2) of the European Communities Act 1972. The instrument will be made under the EU (Withdrawal) Act 2018 and the relevant explanations are set out in section 7 of this memorandum.

3.2 The DHSC regrets that unfortunately the provisions of this instrument breach the rule that provisions of statutory instruments subject to the negative procedure should normally have been laid before Parliament 21 days before they come into force ("the 21-day rule"). It was considered necessary that the regulations in this instrument come into force on 1 January 2022 to ensure patients across the UK are able to maintain equitable access to MHRA authorised prescription only medicines beyond 1 January 2022. From 1 January 2022, in accordance with the terms of the Northern Ireland Protocol (NIP), NI will continue to meet the requirements of the majority of the EU regulatory framework on medicinal products, namely the EU Pharmaceutical Acquis. This framework will no longer apply in GB and the MHRA will operate outside the EU regulatory network in respect of GB.

3.3 Under the NIP, medicines manufacturers serving both the GB and NI markets will have to comply with two different regulatory regimes, adding costs and complexity to distribution.

3.4 The Government continues to work intensively towards a negotiated solution with the EU. Due to the ongoing and sensitive nature of these discussions we have had to make a legislative proposal for new arrangements for 1 January 2022, which does not meet the 21-day rule.

3.5 As discussions continue, NIMAR will ensure that if a prescription only medicine has been assessed as safe for patient use by the MHRA, patients in NI can continue to have access to this medicine, if supply to NI is discontinued by a manufacturer.

3.6 This supports the ongoing objectives of both the EU and the UK. NIMAR is fully compliant with UK law, with the Northern Ireland Protocol, and with EU rules. DHSC accordingly hopes the committee will consider the reasons outlined and find them as reasonable justification in the circumstances.

4. Extent and Territorial Application

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

4.2 The territorial application of this instrument is all of 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 EU has created a comprehensive code for the marketing, manufacturing, packaging, distribution, advertising and monitoring of human medicines. The framework for this is set out in Directive 2001/83/EC and Regulation (EC) No. 726/2004. There are also multiple pieces of Commission-made EU tertiary legislation - both directives and regulations, largely made under Directive 2001/83/EEC or regulation (EC) No. 726/2004, as well as some further EU regulations that supplement the EU legislative framework on human medicines.

6.2 Directive 2001/83/EEC and the tertiary directives on human medicines have all been transposed into UK law by the Human Medicines Regulations 2012 ('HMRs'). The HMRs were made under section 2(2) of the European Communities Act 1972 ('ECA').

6.3 Article 5(4) and Annex 2 to the NIP provide that legislation listed in that Annex applies to and in the United Kingdom in respect of Northern Ireland. Paragraph 20 of the Annex sets out the applicable EU legislation relating to medicinal products; this list includes Directive 2001/83/EC, Regulation 726/2004 and Article 13 of the Clinical Trials Directive (which regulates the manufacture and importation of investigational medicinal products that are used in clinical trials).

6.4 The MHRA, an executive agency of DHSC, carries out the functions of competent authority in the UK in the area of human medicines on behalf of the "licensing authority", a body established under regulation 6 of the HMRs.

6.5 This instrument will be made under Section 8C of the EU (Withdrawal) Act (2018).

6.6 NIMAR is derived from Article 5(1) of Directive 2001/83/EC, which provides an exemption for medicinal products from the application of the Directive, where the product is required to fulfil special needs. In practice this means that, with certain controls, a medicinal product is exempt from the requirement to have a marketing authorisation to be placed on the market and the EU's importation and falsified medicine requirements do not apply.

6.7 Under the terms of Article 5(1), a direct relationship must be identified and recorded between the professional and the patient. For this reason, prescription only medicines are eligible for supply via NIMAR, with the written prescription fulfilling the direct relationship requirement.

7. Policy background

What is being done and why?

7.1 Under the terms of the Northern Ireland Protocol (NIP), NI must continue to meet the requirements of the EU regulatory framework on medicinal products, namely the EU Pharmaceutical Acquis, with the MHRA regulating medicines on that basis.

7.2 NI is highly dependent on medicines supplied from GB. Whilst negotiations between the EU and the UK on the Northern Ireland Protocol continue, NIMAR introduces a new regulatory route to supply GB medicines to NI, derived from Article 5 (1) of Directive 2001/83/EC. NIMAR will ensure that if a prescription only medicine has been assessed as safe for patient use by the MHRA, patients in NI can continue to benefit from access to this medicine. This supports the ongoing objectives of both the EU and the UK.

Functionality

7.3 NIMAR will allow prescription only medicines which are authorised by the MHRA for use in GB to be supplied from GB to NI, where it is considered that clinical needs in Northern Ireland for the product may be unmet (for example if there is no NI licensed alternative available). All medicinal products will have met the MHRA's stringent requirements for safety, quality and efficacy.

7.4 Eligibility will be determined by a DHSC/NIE assessment of clinical need in NI, and if it is deemed that NI patient need cannot be met with supply of licensed products, the active substance(s) will be placed on a publicly available NIMAR list. To be eligible for supply via NIMAR, one of the conditions is that the medicinal product is subject to a UK marketing authorisation (either for GB or the UK).

7.5 The list of eligible products will be reviewed on an as-needed basis and it is expected that products will be retained on the list for a reasonable period to provide stability in the NI market. We envisage that new products can be added to or removed from the NIMAR list at any time as required.

7.6 Products supplied via NIMAR are to be used by NI patients on the same terms as patients in GB. Given this principle, the MHRA is confident that prescription only medicines supplied under NIMAR do not pose any greater risk to patient safety compared to medicines supplied on a licensed basis, as all products will have been authorised for use in GB by the MHRA.

7.7 As mentioned, some of the amendments made by this instrument place an obligation on the licensing authority to publish a list of NIMAR products for the purpose of

supplying NIMAR products to Northern Ireland. We consider this sub-delegation to be appropriate to ensure clinical needs are met in Northern Ireland, to ensure that the provision of healthcare in the UK is equitable and to maintain transparency.

Public interest

7.8 NIMAR is designed to ensure that NI citizens have access to the same prescription only medicines and innovative products as citizens in GB. This is essential to ensure that healthcare provision across the UK is equitable.

Explanations

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

7.9 Medicines are currently being supplied to Northern Ireland in compliance with the requirements of the Human Medicines Regulations 2012. NIMAR is a new medicine supply route specifically to address situations of clinical need in Northern Ireland.

Why is it being changed?

7.10 This instrument is required in order to establish an additional regulatory route to facilitate equitable supply of prescription only medicines to Northern Ireland.

What will it now do?

7.11 The instrument will facilitate the supply of prescription only medicines from GB (which are licensed) to NI (where they are unlicensed), where there is no licensed alternative available, from 1 January 2022.

8. European Union Withdrawal and Future Relationship

8.1 This instrument is being made using the power in section 8C of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

9. Consolidation

9.1 Consolidation will not be done for this instrument.

10. Consultation outcome

10.1 In order to ensure the development of a regulatory pathway that is operationally viable MHRA and DHSC have consulted with a number of actors across the medicines supply chain.

10.2 We have worked with the Chief Pharmaceutical Officer in the Department of Health NI to engage with stakeholders in Northern Ireland. We have also engaged directly with UK representative stakeholders, including the General Medical Council (GMC), Pharmaceutical Society of Northern Ireland (PSNI), and appropriate industry trade associations.

10.3 Consultation responses were broadly supportive of this statutory instrument. Concerns were raised by stakeholders on the need to comprehensively brief prescribing physicians. We will continue to collaborate with relevant member organisations to achieve this in early 2022.

11. Guidance

11.1 The gov.uk website provides MHRA guidance to industry partners. This guidance is consistently reviewed and updated in line with necessary changes and in response to queries from industry about its clarity. Those subscribing to the guidance pages will be alerted when updates are published.

11.2 We will publish additional guidance following the laying of this instrument.

11.3 The guidance is important to ensure that all supply chain actors are aware of the process that will follow once a product has been added to the NIMAR list and subsequently supplied to NI. It is essential that industry partners can clearly access, understand and enact changes based on the guidance.

11.4 There are additional customer service functions available through the MHRA website to allow industry partners to submit queries and receive a direct response from the MHRA.

12. Impact

12.1 The impact on business is not significant. A Regulatory Triage Assessment was undertaken, and it was deemed that a full Impact Assessment was not necessary. Partners involved in the medicines supply chain including, but not limited to, manufacturers, wholesalers, distributors and pharmacies will be required to familiarise themselves with this new regulatory route and recognise when and how to enact it. However, we anticipate that it will be used for only a limited number of medicines and therefore that the overall impact on business will not be substantial.

12.2 There is no significant impact on the public sector.

12.3 As the impact to businesses was below the +/- £5 million threshold, a full Impact Assessment would not be proportionate and hence a more high-level Regulatory Triage Assessment was carried out.

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 minimize the burden on small businesses.

13.3 The basis for the final decision on what action to take to assist small businesses is that, as noted in 12.3, the impact to business is below the +/- £5 million threshold. Therefore, it was judged that while the policy will impact small businesses, this will not be of substantial consequence to their activities and supporting measures are not required.

14. Monitoring & review

14.1 The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State. As this instrument is made under the European Union (Withdrawal) Act 2018 no review clause is required.

15. Contact

15.1 Hannah Gain at the Medicines and Healthcare products Regulatory Agency, email: Hannah.gain@mhra.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Jack Turner, Deputy Director for EU and International Policy at the Medicines and Healthcare products Regulatory Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Edward Argar MP, Minister of State 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	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.

		to include these statements alongside all EUWA Sis	
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)	Paragraph 15, Schedule 8	Anybody making an SI after IP completion day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate	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.

ECA 1972		legislation made under s. 2(2) ECA	

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.