EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENTS RELATING TO THE WINDSOR FRAMEWORK) REGULATIONS 2024

2024 No. 832

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.

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

2. Declaration

2.1 Minister Andrew Gwynne, Parliamentary Under-Secretary of State for Public Health and Prevention at the Department of Health and Social Care, confirms that this Explanatory Memorandum meets the required standard.

2.2 Fionn Craig, Deputy Director for EU Regulations, Devolution and the Union at the Department of Health and Social Care, confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Maria Jones at the Department of Health and Social Care Telephone: 020 7484 9417 or email: dacdot@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends the Human Medicines Regulations 2012 (S.I. 2012/1916) (HMRs) to reflect the Windsor Framework agreement for medicines.

4.2 Under the Windsor Framework, the United Kingdom (UK) and the European Union (EU) agreed a set of solutions to safeguard the supply of medicines to Northern Ireland (NI).

4.3 The EU has introduced a Regulation (Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in NI and amending Directive 2001/83/EC) to give effect to the agreed solution in EU law.

4.4 This instrument makes the changes necessary to, and consequential upon, the Windsor Framework.

4.5 This instrument makes the following specific changes:

a. It provides that a "UK marketing authorisation" comprises the following different types of authorisation: UKMA(UK)(Category 1) and UKMA(Category 2), which permit marketing of a medicinal product in all the

territories of the UK. There are also provisions for: a UKMA(GB) which permits marketing of a medicinal product in Great Britain (GB) but does not extend to NI and UKMA(NI) which permits marketing of a medicinal product in NI but does not extend to GB. A UKMA(GB) can be designated by the Medicines and Healthcare products Regulatory Agency but cannot be applied for. Both UKMA(GB) and UKMA(NI) licences are expected to be rare.

b. It disapplies various EU labelling requirements that were introduced by the Falsified Medicines Directive 2011/62, including certain safety features required by Directive 2001/83, the product identification and anti-tampering device rules and detailed rules for the safety features appearing on the packaging of medicinal products for human use which are contained in Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council.

c. It provides for a new requirement that all medicines placed on the market in the UK must be labelled "UK only".

Where does the legislation extend to, and apply?

4.6 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the whole of the UK.

4.7 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the whole of the UK.

5. Policy Context

What is being done and why?

5.1 When the original Northern Ireland Protocol was agreed, medicines regulations were included in Annex 2, which meant that EU medicines regulations applied in full to NI. This created risks to the supply of medicines from GB to NI, the route through which almost all medicines are supplied, by introducing a range of new regulatory barriers. To prevent discontinuations of medicines to NI and to safeguard public health in NI, solutions to several pressing issues were agreed with the EU in April 2022 and changes were implemented in EU law. This protected medicines supply to NI in the short term, but significant longer-term risks remained.

5.2 While the EU was responsible for licensing all novel medicines in NI, there was a risk of different medicines being available in NI and GB. It also created a risk to NI, as it is not financially viable in many cases, for suppliers to produce a separate NI-only pack, leading companies to potentially withdraw from the NI market.

5.3 The application of the EU's Falsified Medicines Directive (FMD) packaging meant barcoding and scanning requirements applied to NI but not GB, creating a disincentive to supply to NI. A temporary derogation on the full application of these FMD measures is due to expire at the end of 2024, which would have been likely to cause the discontinuation of a large number of medicines to NI.

5.4 These remaining issues were addressed as part of the Windsor Framework Agreement in February 2023.

What was the previous policy, how is this different?

5.5 Currently, the European Commission licenses some medicinal products for NI and FMD measures, requiring a unique identifier that needs to be scanned at various

points along the supply chain, are applied to products, though with a derogation in place so products can move through GB to NI without being decommissioned from the FMD system. In GB, the Medicines and Healthcare products Regulatory Agency (MHRA) licences medicinal products and FMD does not apply.

5.6 The Windsor Framework introduces a UK-wide licensing regime, meaning that the same medicinal products, in the same packs with the same labels, will be available across the whole UK, without the need for separate licensing and packaging requirements. The MHRA can license all medicines across the UK, including novel medicines such as cancer medicines, which under the original Protocol had to be authorised for NI by the European Commission. The EU rules around FMD are permanently disapplied in NI.

5.7 To preclude onward movement of these medicines into any part of the EU, while ensuring medicines use the same packaging and labelling across the UK, all medicines on the UK market must be labelled as 'UK Only'.

5.8 NI's pharmaceutical industry will continue to have full access to both the UK and EU markets. Businesses in NI will continue to be able to manufacture and sell products on the EU market as they do now.

6. Legislative and Legal Context

How has the law changed?

6.1 The HMRs govern the arrangements across the UK for the licensing, manufacture, wholesale dealing and sale or supply, advertising and post-marketing monitoring of medicines for human use. Together with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the surviving provisions of the Medicines Act 1968, they set the essential framework for the regulation of medicines for human use in the UK.

6.2 Under the current arrangements, the HMRs implement the Directive 2001/83/EC on human medicines; and provided for a system in which there are three types of marketing authorisation: UKMA(UK), UKMA(NI) and UKMA(GB), with EU law applying (along with the domestic regulations) to the first two of those categories; and UK law only to GB authorisations. This was partly as a result of the requirement under EU law (applicable in relation to NI under Article 5(4) of the Windsor Framework) that certain medicines may only be authorised across the EU and NI on a centralised basis by the European Commission (on the recommendation of the European Medicines Agency) (the "centralised procedure").

6.3 This instrument amends the HMRs to allow the UK regulator (MHRA) to license all medicines across the UK. Consequently, medicinal products that would previously have fallen within the scope of the centralised procedure must now be authorised by the UK regulator in accordance with the law of the UK.

6.4 This instrument provides for two categories of UK-wide marketing authorisation (Category 1 and Category 2). EU law, in a significantly amended form following the April 2022 agreement and the Windsor Framework, will continue to apply (along with the domestic regulations) to those authorisations that fall into Category 2 (including many well-established medicines); and only UK law will apply for those that fall into Category 1 (including novel medicines). In addition, this instrument:

a. disapplies the FMD requirements, including certain safety features required by Directive 2001/83/EC and the product identification and anti-tampering device rules contained in Commission Delegated Regulation (EU) 2016/16; and

b. provides for a new requirement that all medicines placed on the market in the UK or NI must be labelled "UK only".

Why was this approach taken to change the law?

6.5 The amendments to the HMRs were the only possible means to make these changes, further to the arrangements agreed between the UK and EU under the Windsor Framework.

7. Consultation

Summary of consultation outcome and methodology

7.1 Although formal public consultation was not undertaken for this Statutory Instrument, there has been extensive engagement with Trade Associations and across the whole pharmaceutical industry, in relation to the implementation of the Windsor Framework for medicines. The changes have been widely and positively received by industry, including the major pharmaceutical trade associations and healthcare professionals.

7.2 Consent was sought from the Northern Ireland Executive to which a positive response was received. Officials have engaged with the Northern Ireland Civil Service on this legislation, who are supportive of the proposed approach.

8. Applicable Guidance

8.1 Guidance on the updated requirements for UK-wide licensing was published on 29 September 2023: UK-wide licensing for human medicines - GOV.UK (www.gov.uk[1]).

8.2 Guidance on the updated requirements for the labelling and packaging of medicinal products was published on 28 July 2023: Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework - GOV.UK (www.gov.uk[2]).

8.3 Existing gov.uk guidance is currently being reviewed and will be updated as appropriate; further updates will be published in the coming months.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is expected to be a moderate positive quantifiable benefit overall but should also be seen in the context of wider societal, business and public sector benefits in avoiding the significant risk of discontinuations or other interruptions in supply. These benefits to human health and the consequent social and economic impact are not quantifiable, unlike the moderate supply chain benefits for businesses, but nonetheless the Government considers these

[1] https://www.gov.uk/government/publications/uk-wide-licensing-for-human-medicines/uk-wide-licensing-for-human-medicines
[2] https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework

to be very significant and important. Charities and the voluntary sector are not expected to be directly impacted by the legislation. The changes set out in the Windsor Framework fall on firms in the biopharmaceuticals sector. One-off costs will be incurred by businesses that hold marketing authorisations for human medicines. These firms will face one-off transitional costs, estimated between £63m and £84m, associated with changing the packaging of their products to comply with the new licensing and labelling requirements. The quantifiable benefits to business will be ongoing, between £6m and £16m each year, arising from the permanent disapplication of the FMD requirements in NI for prescription medicines. This change will offer efficiency gains for wholesalers and community pharmacists by removing and avoiding the need for prescription medicine packs to be "decommissioned" and processed separately from medicines supplied to GB through the supply chain. There are also unquantifiable significant benefits arising from the long-term uninterrupted supply of medicines to NI. Businesses will benefit in the long term from simplification of the regulatory environment and being able to produce a single pack for the whole UK for all types of medicine.

9.3 The legislation does impact small or micro businesses. It is not possible to exempt small or micro businesses from the requirements of regulation.

9.4 All affected products require new licences and packaging to comply with the agreed terms of the Windsor Framework. The scale of business impact depends on the number of licences a firm holds, smaller businesses are likely to hold fewer licences.

9.5 The impact on the public sector is significant but largely unquantified. Patients in NI and the public sector will benefit from the reduced risk of medicines supply shortages in NI which would create serious disruption for patients in accessing treatment with consequences for public health. This long-term solution also means UK patients will be treated by the same medicines on the same terms, addressing the risk of inequitable medicines access in different parts of the UK. Public sector healthcare providers in NI will realise benefits from improved access to medicines for prescribing and efficiencies from the disapplication of FMD requirements.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 This instrument is made under the European Union (Withdrawal) Act 2018 which means no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument amends the HMRs which were made under section 2(2) of the European Communities Act 1972.

11.2 There will be one-off costs incurred by businesses that hold UK Marketing Authorisations, who will need to notify the MHRA, providing the product artwork to indicate on the packaging where 'UK Only' is to be located. We have worked with businesses to allow different options for this to ensure it can be done in the most cost-effective and efficient ways for businesses. The fee is up to £410.00, with a reduced rate for bulk applications of up to 25 products.

11.3 As part of the World Trade Organisation Technical Barriers to Trade Agreement, this instrument was notified to WTO members and no objections were received. Pursuant

to that Agreement, the UK is required to provide for a six-month implementation window between the laying of a Statutory Instrument, and the coming into force of the new measures it contains. This Statutory Instrument is due to come into force on 1 January 2025, and consequently was due to be laid on 1 July 2024. The laying date was postponed due to the General Election announcement.

12. European Convention on Human Rights

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

13. The Relevant European Union Acts

13.1 This instrument is made using powers contained in section 8C of the European Union (Withdrawal) Act 2018 and relates to matters arising out of, or related to, the Windsor Framework formerly 'The Protocol' as a result of the withdrawal of the UK from the European Union

13.2 This instrument brings into force the regulatory changes required to resolve the threats to medicine supply to NI, that were introduced by the agreement of the Windsor Framework.