**EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION OR DOCUMENT WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK**

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland.

**COM(2023)122**

Submitted by the Foreign, Commonwealth and Development Office

17 April 2023

**SUBJECT MATTER**

1. Under the Windsor Framework, the UK and EU have negotiated a set of solutions to safeguard the supply of medicines to Northern Ireland.

2. The proposed Regulation would give effect to these solutions, in accordance with the terms of the Windsor Framework.

3. The original Northern Ireland Protocol posed significant issues for medicines supply to Northern Ireland, though stable supply has been secured up until now as a result of action by the UK and EU. Some issues posed by the original Protocol were addressed by legislation brought forward by the EU in April 2022, and others were ameliorated on a time-limited basis such as the temporary derogation on the EU's Falsified Medicines Directive. The UK also made legislative and regulatory changes, introducing the Northern Ireland MHRA Authorised Route to help support medicines supply.

4. However, the action taken did not constitute a stable basis for long-term medicines supplies. As such, and as part of the Windsor Framework, the UK and EU reached agreement on a stable, long-term solution to safeguard the supply of medicines into Northern Ireland. This ensures that medicines licensing will always be undertaken by the UK regulator for patients in Northern Ireland, without jeopardising access for Northern Ireland pharmaceutical firms to the EU market.

5. The proposal outlines agreed solutions to these issues, to provide that:
    a. The safety features (such as a 2D barcode) required under EU falsified medicines legislation will not appear on medicines for the Northern Ireland market, and all of the associated rules are disapplied, including Commission Delegated regulation 2016/161. This does not affect the UK's ability to introduce its own FMD system or other forms of safety features for UK-approved products. This will mean that all types of medicines can be supplied in single packs, within UK supply chains.

b. The EU's Centralised Procedure will no longer apply to novel medicines in Northern Ireland, meaning the UK Medicines and Healthcare products Regulatory Agency (MHRA) can licence all medicines in the UK.

6. The proposal also outlines some agreed safeguards, to ensure that medicines licensed for use only in the United Kingdom will not be made available in the EU. This includes ensuring that medicines intended to be placed on the market in Northern Ireland be labelled as "UK only", reflecting that all UK medicines will be licensed UK-wide, as well as that the underlying efficacy of the UK regime will operate in line with international standards.

7. If agreed, the proposed Regulation will apply in relation to Northern Ireland.

## SCRUTINY HISTORY

8. No recent relevant scrutiny history.

## MINISTERIAL RESPONSIBILITY

9. The UK Secretary of State for Health and Social Care and the Northern Ireland Minister of Health are responsible for the grant, renewal, variation, suspension and revocation of licences and authorisations under the Human Medicine Regulations 2012.

## INTEREST OF THE DEVOLVED ADMINISTRATIONS

10. The subject matter of this Explanatory Memorandum (EM) relates to medicines, which is a transferred matter in Northern Ireland and a reserved matter in the rest of the UK. The MHRA is the regulator for the whole UK.

11. The EM relates to medicines supply to Northern Ireland pursuant to the Windsor Framework.

12. DHSC has been engaging closely with the Department of Health in Northern Ireland to discuss the issues affecting medicines supply, and that engagement has informed discussions with the EU Commission. DHSC has also discussed the proposed changes with the Department of Health in Northern Ireland. DHSC will continue to engage colleagues in the Northern Ireland Civil Service on the application of this proposal.

## LEGAL AND PROCEDURAL ISSUES

i. Legal Base: The legal base of the Regulation is Article 114 of the Treaty on the Functioning of the European Union.

ii. Timetable for adoption and implementation: If agreed, the proposed Regulation will commence subject to further engagement between the UK and EU. The proposal sets out a target commencement date of 1st January 2025.

iii. The subject of this proposal is relevant to retained EU law in that it will require amendment to the Human Medicines Regulations 2012, which are retained EU law under section 2 of the European Union (Withdrawal) Act 2018.

## POLICY IMPLICATIONS

13. The proposed Regulation will make provision in relation to medicines that are to be licensed for supply to Northern Ireland, in the process disapplying those provisions of EU law that otherwise precluded the UK-wide licensing of medicines.

14. Firstly, Article 4 of the new EU regulation will provide that EU authorisations (granted under EU Regulation 726/2004) of novel medicines will not be valid in Northern Ireland, setting out instead that such products can be supplied in Northern Ireland only on the basis of a UK licence. To avoid these medicines being used elsewhere, the UK will ensure all medicines are labelled as “UK only”. The UK will also provide assurances about the underlying efficacy of the UK’s medicines regulatory regime. As a result of these changes, patients in Northern Ireland will be able to receive the same medicines as patients in the rest of the UK. The UK medicines regulator, the MHRA, will now be able to licence all medicines for the whole UK in line with UK policy objectives. This removes the role of the European Medicines Agency (EMA), which has hitherto been the sole authority licensing novel medicines, like cancer drugs, in Northern Ireland. This addresses concerns raised by industry and the health and care sector about divergence in licensed indications between the EMA and MHRA.

15. Secondly, Article 3 of the new Regulation disapplies the provisions in the Human Medicines Directive (2001/83/EC) that relate to the EU falsified medicines safety features, and also Commission Delegated Regulation 2016/151 which sets out the detailed operation of the safety features for human medicines. This means that requirements under the Falsified Medicines Directive will no longer apply for medicines across the UK supply chain, replacing the previous temporary derogation during the grace period that prevented medicines moving through Great Britain to Northern Ireland being decommissioned, but still requiring the physical safety features on packs. Removing the EU safety features from packs of medicines in Northern Ireland altogether helps to ensure that companies can produce a single pack for the whole UK, responding to issues industry have raised around the requirement to produce a separate pack for Northern Ireland. The disapplication of these provisions also brings Northern Ireland in line with Great Britain and provides a stable long-term solution, in line with the clear requests from stakeholders.

16. The prior disapplication of EU rules made through Directive 2022/642, as part of previous discussions on the old Protocol, are carried forward. This means the location of regulatory functions such as batch-testing of medicines

intended for supply in Northern Ireland and the place of establishment of the licence holder can continue to be in Great Britain and no additional processes will be required in order to supply medicines in Northern Ireland.

17. The changes outlined in the proposal reflect that it is an essential state function for the UK to maintain and oversee the supply of medicines within the whole UK. The MHRA will now be able to licence all medicines for supply in the UK, with all key regulatory functions related to supply taking place within the UK.

18. Both the UK and the EU adhere to international standards on medicines, which the UK helped to shape through the appropriate international bodies. Furthermore the UK Government has no intention of ever compromising on the safety and efficacy of medicines. The UK will provide written assurance to the Commission to that effect as part of the solution.

19. The UK and EU have agreed a target date for implementation of 1 January 2025. Our assessment is that this should provide sufficient time for industry to prepare and adapt to new requirements, based on stakeholder feedback. We will work with industry and other stakeholders to set out more detail on these arrangements; to help prepare for the changes ahead; and ensure that we have provided clarity and certainty on the way forward as we transition to a UK regime.

20. In due course, the UK will also amend the Human Medicines Regulations 2012 (SI 2012/1916) so that they are consistent with this proposed Regulation and operating a UK-wide licensing regime. MHRA will also publish guidance to support industry in preparing for the commencement of this proposal.

## CONSULTATION

21. This proposal is the result of bilateral UK and EU discussions.

22. DHSC has been engaging regularly with external stakeholders, including in industry and the Northern Ireland Civil Service, to inform the issues and solutions that this proposal seeks to address. Many stakeholders have publicly welcomed the changes that would be made as part of this proposal.

## FINANCIAL IMPLICATIONS

23. The solutions outlined in this proposal will require all companies wishing to place their product on the market in the UK to adapt their supply chains and conform to new requirements, in line with operating a UK-wide licensing regime for all medicines.

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