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

COM (2024)43

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of EUDAMED, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical devices.

Submitted by Department of Health and Social Care 14 May 2024

SUBJECT MATTER

1. Regulation (EU) 2017/745 (the 'Medical Devices Regulation' (MDR)) and Regulation (EU) 2017/746 (the 'In Vitro Diagnostic Medical Devices Regulation' (IVDR)) of the European Parliament and of the Council set the regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs) for EU member states. Under the terms of the Windsor Framework, both have applied directly in Northern Ireland since 26 May 2021 and 26 May 2022, respectively.

2. In January 2022, the European Parliament and the Council adopted a staggered extension of its transitional period for IVDs to comply with the substantial changes to the regulatory framework under IVDR. At present, the transition period should end on the following dates: 26 May 2025 for Class D devices, 26 May 2026 for Class C devices, 26 May 2027 for Class B devices and Class A devices placed on the market in sterile condition, and 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

3. In January 2024, the European Commission published this Proposal (COM/2024/43), which outlines three amendments to the MDR and IVDR legislation:

    a. Firstly, it aims to further extend the transitional period for certain IVDs to mitigate the risk of shortages of these products, especially of high-risk IVDs.

    b. Secondly, the proposal introduces a gradual roll-out of the EU's electronic database on medical devices (EUDAMED), with each EUDAMED module becoming mandatory once it has been audited and declared functional, instead of deferring until all six modules are complete. Mandatory use of available modules could start from Q4/2025.

    c. Thirdly, the proposal aims to mitigate supply disruption by introducing a requirement on manufacturers to inform their relevant Competent Authority and health institutions before they cease (temporarily or permanently) the supply of a critical medical device, other than a custom-made device.

4. Qualifying Northern Ireland Goods may continue to be placed on the Great Britain market with a valid CE marking on an indefinite basis. This arrangement is a result of the Government's

commitments to Northern Ireland's unfettered access to the market in the rest of the UK and is underpinned by the UK Internal Market Act 2020.

SCRUTINY HISTORY

5. Previous EU legislation relating to the extension of the transitional arrangements for certain medical devices and in vitro diagnostic medical devices has been subject to scrutiny as EU documents 5139/23, COM (23)10 adopted as Regulation (EU) 2023/607 and 12284/21, C(21)627 adopted as Regulation (EU) 2022/112. DHSC submitted EMs on 10 February 2023 and 11 November 2021 respectively. There were no questions arising from the examination of both documents from either of the two EU Scrutiny Select Committees.

MINISTERIAL RESPONSIBILITY

6. Minister Stephenson

   Minister of State for Health and Secondary Care

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

7. The regulation of medical devices is a reserved matter under the devolution settlements. Under the terms of the Windsor Framework, the EU legislation that applies in Northern Ireland is listed in Annex 2 to the Framework and includes the MDR and IVDR. By virtue of Section 7A of the EUWA, both the MDR and IVDR apply directly in Northern Ireland.

8. The MHRA continues to actively engage with the Northern Ireland Department of Health and Devolved Governments in its work to develop the future regulatory framework for medical devices in the UK.

LEGAL AND PROCEDURAL ISSUES

9. **Legal Bases:** The proposal is based on Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union (TFEU).

10. **Voting Procedure:** This legislation is being adopted via the ordinary legislative procedure. Therefore, the Council of the European Union will vote by qualified majority.

11. **Timetable for adoption and implementation:** The legislative proposal was adopted by the European Commission on 23 January 2024 and the First Reading was completed by the Council of the European Union on 22 February 2024. The next step will be consideration by the European Parliament. Under Article 3, Regulation will enter into force on the day of its publication in the Official Journal of the European Union ("OJEU"), except for Article 1, point (1), and Article 2, point (1), which shall apply from six months after the Regulation comes into force.

POLICY AND LEGAL IMPLICATIONS

12. With regards to the first amendment to further extend the transitional period for certain IVDs, this will alleviate pressure on manufacturers in both Great Britain and Northern Ireland, to ensure they have more time to conduct the necessary conformity assessments to gain CE certification under IVDR. High-risk IVDs still continue to have the highest level of scrutiny and must meet high safety standards in order to be placed on the market. Therefore, there should

not be any negative impact on public health and patient safety as a result of this provision, and this provision should support businesses transitioning to the new requirements.

13. With regards to the second amendment covering a gradual roll-out of the six EUDAMED modules as they are declared functional, the first three EUDAMED modules have been available for voluntary use since December 2020 (Actors) and October 2021 (UDI/Devices; Notified Bodies/Certificates). Two further modules (Market Surveillance; Post-Market Surveillance and Vigilance) are expected to be completed in Q2/2024. The last module (Clinical Investigations/Performance Studies) will not be completed before Q3/2026. EUDAMED will be used by manufacturers, authorised representatives, importers and other actors to report relevant information pertaining to medical devices on the EU and Northern Ireland markets. The Competent Authorities, including the MHRA, will be able to monitor the placement and use of devices on the market to ensure public health and patient safety.

14. The current proposal suggests the mandatory use of available modules could start from Q4/2025. It is anticipated that this will support the MHRA's obligations to fulfill its role as the Competent Authority for medical devices in Northern Ireland and ensure patient safety, including through enhancing transparency. Some additional resource and training may be required to scale up adoption when these modules become mandatory both in Government and for suppliers.

15. The previous date given by the EU for mandatory use of EUDAMED was 2027, when all modules are fully functioning, whereas the new provision means economic operators may need to start using some modules from Q4 in 2025. The MHRA will help to facilitate a smooth transition through proactive engagement with trade associations, and business groups to provide clear communication on access and reporting requirements.

16. There may be a need to introduce secondary legislation domestically to ensure arrangements are in place for device registration and reporting to the EUDAMED system, once the relevant modules are declared functional under the proposed gradual roll-out approach. With regards to the third amendment, we do not expect prior notice to have any negative impact or place additional burden on IVD manufacturers and businesses in Northern Ireland or those supplying to Northern Ireland. This information would enable the MHRA and relevant health institutions to mitigate any impact that shortages of certain medical devices in Northern Ireland may have on patient safety and public health.

CONSULTATION

17. The MHRA and DHSC have close working relationships with the Northern Ireland Civil Service and regularly engage with the Northern Ireland Department of Health on medical device regulations. The MHRA and DHSC will continue to engage with them on the proposed amendments to ensure a smooth transition.

FINANCIAL IMPLICATIONS

18. The European Commission has suggested that the proposed changes will have no budgetary implications. The proposal was not accompanied by a dedicated impact assessment because the limited changes relate only to the gradual roll-out of EUDAMED and the extension of the IVDR transitional period, without altering the MDR or IVDR in substance.

19. *For suppliers:* There is an expenditure to businesses for renewing In Vitro Diagnostic Directive (IVDD) EC Certificates, should existing certificates expire before the new transitional date. Exact costs are set by Notified Bodies, which are private companies. This proposal extends the transition period, so no new costs are incurred.

20. *For suppliers:* As outlined above, there could be additional costs required by suppliers for implementing EUDAMED provisions once mandatory reporting is instated. Further analysis is needed to understand the full financial implications on actors.

21. *For Government:* For MHRA, there will be costs involved in adopting the necessary IT infrastructure for functional EUDAMED usage and ensuring interoperability for information sharing. Further analysis is needed to understand the full financial implications involved for the full scope of this proposed legislation.

22. *For Government:* Additional resource may be required for stakeholder engagement and guidance development to help facilitate a smooth transition and reduce regulatory burden on businesses.

Rt. Hon Andrew Stephenson CBE MP

Minister of State Health and Secondary Care