PUBLISHED REPLACEMENT EU ACT
INITIAL ASSESSMENT OF IMPACT

DSC REF: DSC-11-2024

Published Replacement EU Act

Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices Text with EEA relevance. OJ L, 2024/1860, 9.7.2024. [link]

This regulation will amend Regulation (EU) 2017/745 [link] and Regulation (EU) 2017/746 [link]; these regulations are referenced at Protocol Annex 2, Heading 21 on Medical Devices. These regulations have fully applied in the EU and in NI since 26 May 2021 and 26 May 2022 respectively and sets a strengthened regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs).

Summary of the Act

This published amending regulation aims to mitigate risks to the supply of medical devices and in vitro diagnostic medical devices (IVDs) in the EU, by:

1. further extending the transitional period for certain IVDs to mitigate the risk of shortages of these products especially high risk IVDs;

2. enabling a gradual roll-out of the electronic systems integrated into the European database on medical devices ('Eudamed') that are finalised, instead of deferring the mandatory use of Eudamed until the last of the six modules is completed; and

3. imposing a requirement on manufacturers to give prior notice before interrupting the supply of certain critical medical devices and IVDs.

Department(s) Responsible

- **Department of Health (DoH, Lead) – Minister Mike Nesbitt**

- **Department for Economy (DfE, Interested) – Minister Conor Murphy**- the Life and Health Science Branch within DfE have been monitoring this

as part of their work leading the Medical Devices Working Group which is attended by the DoH and InvestNI.

Initial Assessment of Impact

Q: Does it appear likely that the application of the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: **No**, there should not be any significant impact to everyday life of communities, in a way that is liable to persist. UKG and DoH collaborative consideration of impact suggests:

- No negative impact on public health and patient safety as a result of this provision, and this provision should support continued GB-NI supply.

- Mandatory use of certain Eudamed modules may have some impact on manufacturers and other economic operators in Northern Ireland, and in Great Britain for actors that supply Northern Ireland due to additional reporting requirements.

- Early warning notifications to the Medicines and Healthcare products Regulatory Agency (MHRA) of manufacturers ceasing supplies will not have any negative impacts for manufacturers and businesses in NI, or those supplying to NI. This information should help mitigate any impact of shortages of certain medical devices in NI which may impact on patient safety and public health.

Q: Does it appear likely that not applying the replacement EU act would have a significant impact specific to everyday life of communities in Northern Ireland in a way that is liable to persist?

A: **Yes,** non-application of the amendments would lead to regulatory divergence between GB and NI and between NI and EU and further confusion to manufacturers leading to possible supply shortages.

UK Government Explanatory Memorandum

The Department of Health and Social Care (DHSC) produced the latest explanatory memorandum (EM) on this topic on the 14 May 2024 – full document attached as Annex 1.

In January 2024, the European Commission published Proposal (COM/2024/43), outlining three amendments to the MDR and IVDR legislation:

- 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.

- 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.

- Thirdly, the proposal aims to mitigate supply disruption by imposing 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.

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.

With regards to the first amendment to further extend the transitional period for certain IVDs. This will alleviate pressure on manufacturers in both GB and NI, to ensure they have more time to conduct the necessary conformity assessments to gain CE certification under IVDR, which will enable them to continue to supply to NI.

With regards to the second amendment to a gradual roll-out of the Eudamed modules that are declared functional – Eudamed will be used by manufacturers, authorised representatives, importers and other actors to report relevant information pertaining to medical devices on the EU and NI market. The previous date given by the EU for mandatory use of Eudamed was 2027 whereas the new provision means economic operators will be required to start using some modules from Q4 in 2025.

The UKG EM indicates that 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. The EM also states 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.

With regards to the third amendment, UKG do not expect prior notice to have any negative impact or place additional burden on IVD manufacturers and businesses in NI or those supplying to NI.

The UKG EM notes financial implications as follows:

- For suppliers: extension of transitional period – no additional cost; mandatory reporting – further analysis needed to understand full cost.
- 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.
- For Government: Additional resource may be required for stakeholder engagement and guidance development.

Analysis by the European Commission on its Impact Assessment

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.

In respect of EC's assessment of impact the proposals EM states that:

- "*Given the urgent nature of this proposal and the limited changes related only to the gradual roll-out of Eudamed and the extension of the IVDR transitional period, it is not accompanied by a dedicated impact assessment. An impact assessment was already carried out when preparing the proposals for the MDR and the IVDR, and this proposal does not alter the MDR or IVDR in substance and does not impose new obligations on the concerned parties. It primarily aims to amend the transitional provisions, giving, under certain conditions, additional time to transition to the IVDR's requirements to avoid shortages and protect public health in the EU*."

Additionally the EC commits to:

- "*continue to closely monitor the progress in the implementation of the Regulations and the impact of the proposed amendments*."

Departmental Engagement

DoH have regularly engaged with DfE, DHSC and MHRA colleagues in respect of medical devices and have contributed, via review, to the drafting of the UKG EM.