Northern Ireland Assembly

Windsor Framework Democratic Scrutiny Committee

OFFICIAL REPORT (Hansard)

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

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Members present for all or part of the proceedings:
Mr Philip McGuigan (Chairperson)
Mr David Brooks (Deputy Chairperson)
Ms Joanne Bunting
Mr Stephen Dunne
Mr Declan Kearney
Ms Emma Sheerin
Mr Eóin Tennyson

Witnesses:

Mr Kevin McVeigh	Department for the Economy
Ms Brenda McGilligan	Department of Health

The Chairperson (Mr McGuigan): I welcome to the meeting Brenda McGilligan, head of the EU future relations branch in the Department of Health, and Kevin McVeigh, head of the life and health science branch in the Department for the Economy.

Mr Kevin McVeigh (Department for the Economy): Thank you.

Ms Brenda McGilligan (Department of Health): Thank you.

The Chairperson (Mr McGuigan): I hand over to you to brief us on the regulation. Fire away.

Ms McGilligan: Thank you, Chair, and good morning members. Thank you for the opportunity to provide the Committee with some background information on EU regulation 2024/1860. Unfortunately, the departmental subject matter expert is unavailable today due to planned leave. My role today is to provide the Committee with background information from a health perspective.

The legislation amends EU regulations 2017/745 and 2017/746, both of which currently apply to Northern Ireland under the Windsor framework. The amendments cover the gradual roll-out of the European database on medical devices, also known as "Eudamed". They provide an obligation for prior notice of interruptions to supplies and extend transitional provisions relating to the supply of medical devices and in vitro diagnostic medical devices (IVDs). Eudamed is already in place, and the

gradual roll-out relates to additional modules of the system. The legislation does not alter the level of risk to supplies of medical devices or IVDs.

As members will be aware from our written submission, the main objective of the regulation is to maintain supply resilience in the EU and across member states. It delivers that in three ways: by further extending the transitional period for certain IVDs, depending on the classification of the device; by enabling a gradual roll-out of the Eudamed database; and by obligating manufacturers to give six months' prior notice to member states and healthcare institutions of any interruptions or discontinuations of medical devices or IVD supplies.

The use of Eudamed for registering economic operators' devices and certificates aims to improve transparency and provide information on devices present on the EU market. The measures aim to deliver a high level of public health protection in the EU and its member states, including patient safety and an avoidance of shortages of IVDs and medical devices. All of those are needed for the smooth functioning of healthcare services.

The Department has been aware of the regulations for some time and has been engaging with the Department of Health and Social Care (DHSC), the Department for the Economy and the Medicines and Healthcare products Regulatory Agency (MHRA). Through that regular engagement, we share the collective view that applying the regulation should not significantly impact on the everyday life of communities in Northern Ireland.

I now hand over to Kevin for DFE's input.

Mr McVeigh: Good morning, Committee. Feedback from industry via Invest NI, which is the operational arm of the Department for the Economy, has been positive. We are in full agreement with Health on the importance of adopting the amendment in Northern Ireland. Brenda has gone through the EU regulation and broken it down into three components. I will look at the two components that impact on industry.

The first amendment relates to further extending the transition period for certain IVDs. It will support businesses that are transitioning to the new requirements, as manufacturers in both GB and NI will have more time to conduct the necessary conformity assessments, which is important.

Secondly, industry understands that the Eudamed system is designed to make the regulatory system more efficient. The amendment will allow the gradual roll-out of mandatory modules from quarter 4 in 2025, rather than having a full roll-out in 2027. Northern Ireland businesses welcome that early adoption.

The MHRA advised that it 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. DFE regularly engages with MHRA alongside colleagues from Health and Invest NI.

At this stage, we are unable to fully determine the financial impacts of adopting the amendment. Although there are no registration costs associated with Eudamed for businesses, they may face additional costs associated with implementing the new system. Those are likely to be administrative costs. Further investigation will be needed to determine the full financial impact. It is important to state at this juncture, however, that there could be economic consequences of not adopting the act, as businesses could be prevented from supplying EU and NI markets.

If members have any questions, we will be happy to answer them.

The Chairperson (Mr McGuigan): Thank you both for that. When the Committee looks at amended or new EU legislation, it has two specific criteria to consider when deciding on whether to have an inquiry. One is whether the legislation will have a significant impact. To summarise what you said, it will have no significant impact from a Health perspective and from an Economy perspective it will have a positive impact.

Mr McVeigh: It will be welcome, yes.

The Chairperson (Mr McGuigan): Thank you.

Ms Bunting: Thank you very much for your evidence, folks; it has been helpful.

I accept and appreciate that any extension to the time frame would be welcome, given the vast impact that it will have. Will you give me some understanding of who was spoken to in the industry? You said that it is likely that any costs will be administrative and that further information is required. What did the stakeholders say about the costs? Are they content with the costs, regardless of what they will be? How do they view the legislation when there is a vacuum in which we do not really know what it will cost?

Mr McVeigh: Thank you for your question. Our arm's-length body is Invest NI. We liaised with it, and it provided the evidence that I gave to the Committee this morning. I cannot extend further than that. Invest NI is regularly in contact with industry on these matters and has gathered its views.

The financial impacts are not known at this stage, but, having taken the potential financial burdens into account, businesses are content that they will not be an impediment to the roll-out.

Ms Bunting: That is fair enough. I just wanted to know whether they had expressed any concern.

Do we have any concept of the potential extent of the costs? It may be that industry is not worried about the costs because it intends to pass them on to the consumer, which could have a bearing on health budgets. Can you give us any idea on the thoughts around cost, so that we can get a greater understanding of what is going on in the industry?

Mr McVeigh: I am not familiar with that. Those are the details that I have been provided with by Invest NI.

Ms Bunting: OK, thank you.

Mr Tennyson: I have a question about our supply chains for the products. Do we have an awareness of whether we are more reliant on products coming in from the European market or on those from the GB market?

Mr McVeigh: I am not familiar with that.

Mr Tennyson: No problem. That is grand, thank you.

The Chairperson (Mr McGuigan): Nobody else has indicated that they want to ask a question. Brenda and Kevin, thank you very much for coming before the Committee to provide evidence and for taking our questions.

Mr McVeigh: Thank you.

Ms McGilligan: Thank you.