Medicines & Healthcare products Regulatory Agency

MHRA

10 May 2021

Open letter from the Medicines and Healthcare products Regulatory Agency regarding importer obligations for Northern Ireland under Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

As you will be aware, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (the 'EU MDR') will apply (subject to transitional arrangements) within EU Member States from 26 May 2021. Under the terms of the Northern Ireland Protocol, the EU MDR will also apply in Northern Ireland from this date. This means that suppliers that import medical devices into Northern Ireland from Great Britain (and other non-EU countries) will need to ensure that relevant requirements introduced through the EU MDR are met. Key requirements, including new obligations that will affect importers, are summarised in MHRA guidance available on gov.uk.

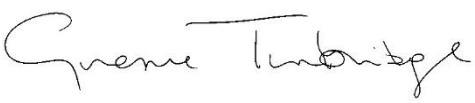
Trade Associations and other industry stakeholders have informed the MHRA that, for many suppliers, the new importer requirements introduced by the EU MDR will create practical and logistical challenges when supplying medical devices to Northern Ireland. While the interpretation of the EU MDR is a matter for the European Commission (and ultimately the European Court), we note that EU guidance on some aspects of the EU MDR has not yet been issued, and that this is creating additional uncertainty as we near the final implementation date.

We therefore recognise that there will be a period of adaptation as suppliers adjust their processes to comply with the new importer requirements, and would emphasise that ensuring continued patient safety and uncompromised patient access to medical devices across the UK, including Northern Ireland, remains our primary aim.

While the MHRA is committed to implementing Regulation (EU) 2017/745 in full, I would like to take this opportunity to reassure stakeholders that, as the Competent Authority for Northern Ireland, we understand the challenges the implementation of these regulations places on stakeholders. As with any new regulations, we know that, for some, there will be operational challenges around aspects of the new rules and the MHRA will take a proportionate approach to compliance in cases where there is no risk to patient safety. This is consistent with how we have approached the implementation of EU legislation in the past. This approach should give suppliers time to adapt to the new requirements.

The MHRA will continue to work closely with stakeholders during this period of adaptation and will support industry's efforts to comply with these new requirements from 26 May 2021 onwards and support the continued safe supply of medical devices to Northern Ireland. We will continue to update our guidance as necessary as and when EU guidance is made available.

If you have any questions about the issues raised in this letter, I would encourage you to refer to the above guidance or to contact the MHRA at devices.regulatory@mhra.gov.uk



Graeme Tunbridge
Director of Devices