Yesterday the Food and Drug Administration (FDA) released a proposed rule that most medical devices distributed in the United States have a unique device identifier, or UDI.

UDI is a code that will either be placed on the device labels, packaging or directly on products. Under the proposed rule, UDI will include a device identifier, which is specific to a device model, and a production identifier, which includes the current production information.

Once the UDI system is fully implemented it will have the potential to improve patient safety by enhancing the quality of information collected in medical device adverse event reports. This will allow for the identification of product problems more quickly and more targeted medical device recalls.

Mike Kreuzer, ABHI’s Technical and Regulatory Executive Director and chair of the Eucomed UDI group (ETF) said, ‘This is an important and long-awaited development that is a significant step towards full traceability and improved patient safety around the globe. The current Revision of the Medical Devices Directives will include a ‘traceability’ requirement, meaning devices will have to carry a unique identifier. Following the PIP scandal, there have been urgent calls for the traceability aspect of the legislation to be brought forward prior to the implementation of the Revision. This legislation will be aligned with that of the United States as part of an initiative to set up a global system for UDI.

UDI programmes are underway in other major markets around the world and will be based on internationally accepted standards which will eventually become a global requirement for devices. To that end, industry must be ready to harness the benefits of UDI, both in terms of supply chain management and patient safety. ABHI welcomes the FDA’s proposed rule and remains closely involved in work at a European level towards UDI development in the EU.’

-END-

Notes to Editor:

The Association of British Healthcare Industries (ABHI) is the industry association for the medical technology sector in the UK. ABHI’s mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes. With over 250 members, ABHI leads the advocacy of the industry in order to advance access to medical technology. Our membership includes some of the leading multinational businesses in the sector in the UK right the way through to small and medium sized enterprises (SMEs). For further details on the UDI proposed rule visit: https://s3.amazonaws.com/public-inspection.federalregister.gov/2012-16621.pdf

Date: 04 July 2012