MEDIMARK® EUROPE NEWS June 2013

The Tangled Destinies of Europe's UDI, Eudamed and Medical Device Regulation

The European Commission published its recommendation for a common framework for a unique device identification (UDI) system for medical devices in April 2013. The announced primary objective of recommendation 2013/172/EU is to improve patient safety by facilitating vigilance, market surveillance and transparency by heightened traceability of medical devices throughout the whole supply chain.

The EU recommendation aligns with the international approach developed by the Global Harmonization Task Force, which has been replaced by the International Medical Device Regulators Forum (IMDRF). The United States is part of the IMDRF, so there is optimism that an internationally accepted and compatible UDI can be achieved. This will increase the potential for comparing incident reporting results associated with each specific medical device at an international level.

Under a UDI system, a series of numeric or alphanumeric characters—device identifiers (static information) and production identifiers (dynamic information)—ultimately will need to be applied to all packaging of all classes of devices. The EU UDI system will be implemented gradually, however, starting with devices in the highest risk category.

The device identifier will be registered by the manufacturer and will be centralised at the European level by means of an electronic UDI system integrated with the future Eudamed database. Production identifiers will be stored at the distributor level.

Whither EUDAMED?

Only national competent authorities currently have access to Eudamed. They primarily use the device module, which contains CE certificates for Class 2a, 2b and 3 devices issued after 2011, Class 1 devices, *in vitro* diagnostic devices, clinical investigation devices and national Competent Authority reports (NCARs).
A report titled, "Evaluation of the "EUropean DAtabank on MEdical Devices," which was published in October 2012, confirmed that Eudamed currently does not provide a comprehensive picture of the EU market, as the number of devices in the database is well short of the approximately 500,000 devices that are actually used in the European Union. Moreover, data entry is incomplete (competent authorities complain about the amount of time involved in entering the data), and Eudamed lacks transparency since the public cannot access it.

This will change with the new Eudamed database, which will align with Europe's electronic UDI. A central registration database, it will allow manufacturers and other stakeholders to enter data directly. Some of the information will be accessible to the general public.

This won’t happen tomorrow. The proposed regulation on medical devices won’t be published until early 2014, at the soonest. After publication, a three-year implementation period starts, and the establishment of an electronic device registration system benefits from an additional 18-month delay.

Patient safety should not suffer as a result of this timeline. I have followed up on hundreds of recalls for my US clients at the behest of competent authorities, and traceability issues either at the company or distributor level were quite rare.

The recommendation 2013/172/EU on a common framework for a unique device identification system (UDI) can be downloaded at : http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF
The report "Evaluation of the “EUropean DAtabank on MEdical Devices” can be downloaded at : http://ec.europa.eu/health/medical-devices/files/pdfdocs/eudamed_evaluation_en.pdf

Written by René Clément