

UDI: What European Companies Should Do Now

Posted in [Medical Labels](#) by Thomas Klein on March 10, 2014



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The current status of UDI implementation? With regard to Europe, one might say: It's complicated.

While the U.S. FDA seems to be on track with the start of the implementation scheduled for September 2014, it is still hard to guess what a timeframe for the EU could look like.

The decision on the revised medical device regulation is still pending, after all. Dutch lawyer Erik Vollebregt, a specialist

in medical technology regulatory issues, says that he doesn't expect any decision before the elections in May. Joël Guillou, director of reimbursement and market logistics at the French industry association SNITEM, ventures the guess that the implementation in Europe will start in late 2016 or even early 2017, and will be completed around 2021.

While the schedule is still open, one thing is certain: UDI will come and manufacturers need to be prepared for it. "Companies should observe very closely what happens in the United States," Vollebregt advises.

"UDI implementation is a very long and specific process, which requires the competence of a skilled team, including regulators, IT and logisticians," according to Guillou. "Manufacturers need to think what there is to organize in their company, in their supply chain and with regard to their customers at a very early stage." Manufacturers should also set up cross-departmental teams to grasp every aspect of the transition.

The benefits of a working UDI system for manufacturers, regulators and patients are obvious: Improved traceability will help them to react more quickly to product failures and facilitate recalls in case of adverse events. In addition, UDI might protect companies from cheap knock-off products. On the other hand, companies have to be aware that the implementation won't come cheap for them.

New labeling systems, reorganisation of data systems, and education of suppliers and customers will cost time and money. Companies might think of outsourcing some of the tasks to external consultants, however. "Perhaps the most important thing is to manage the budget," cautions Guillou. "You have to

think about many years in advance what you have to spend and when and why."

-- By [Thomas Klein](#), Managing Editor, EMDT