EUDAMED: Actor Registration module now scheduled to become available at the start of December 2020

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EUDAMED is a product and manufacturer database in which manufacturers must be entered in accordance with the new European regulations for the development, manufacture, marketing and product surveillance of medical devices in the EU, in the form of MDR and IVDR data.

This information was originally to be entered on the date when the MDR was to enter into application (26 May 2020), with EU lawmakers providing for an 18-month transitional period. But last October, the Commission postponed EUDAMED's launch by two years out of concerns that the system would not be ready on time for the original target date in March 2020. This postponement did not affect the effective date of the MDR itself, which is (currently) scheduled to enter into effect on 26 May 2021.

The database is designed to monitor the safety and effectiveness of medical devices as part of the now-postponed Medical Device Regulation. In March, the MDCG (Medical Device Coordination Group) and the Commission agreed to release the six modules (which make up EUDAMED) on a continuous basis as soon as they become available.

The Commission estimated at that time that the Actor Registration (ACT) module would be ready by March 2021. Part of this plan was recently changed, and the Actor Registration module is now scheduled to become available in early December 2020.

The MDCG is now preparing the industry for the launch of the module, which will allow product manufacturers, authorized representatives and importers to obtain the SRN (single registration number) which they will eventually need to qualify for certificates.

Since there will now be almost 18 months between the time the module is launched and the launch of the complete EUDAMED system, organizations will now have more time to obtain the SRNs they will need in order

to use the database's other functions. This would represent a clear improvement in the situation, particularly given the recent concerns that member states would have to validate all registration requests within two months.

The launch of this module is to be the first in a series of steps leading up to the launch of the full EUDAMED system. Two additional modules (UDI – Unique Device Identification, and CRF – Certificate) will be activated by May 2021, as the Commission works towards its goal of having the system ready to go on time in order to bring the database online in 2022. In preparation for the launch, the Commission published a fact sheet last month with detailed information about EUDAMED, which will be available to the public. A guidance document for users of the EUDAMED database can be found here.

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