EU Addresses Regulation of “Standalone Software” as a Medical Device

Commission Clarifies That Standalone Software May be Classified as Medical Device When Influencing Another Device

Recognizing the need for a clear European legal framework for the regulation of standalone software as a medical device, the European Commission recently clarified its view on the types of standalone software that may be regulated as a medical device in the EU. In particular, the Commission suggests that standalone software systems resulting in specific actions being taken on an existing device and influencing the use of that device may be considered as falling within the scope of EU medical device legislation.

The clarification appears in an updated manual on borderline and classification issues related to medical devices (link), which provides examples of products included in (or excluded from) the scope of the EU’s medical device legislation. The update, which supplements the Commission’s MEDDEV guidance documents (link), is a “tool” to assist Member States in determining when a given product is considered a medical device, and when it is not. The term “standalone software” is defined as “software which is not incorporated in a medical device at the time of its placing on the market or its making available.”

The updated manual demonstrates that the EU aims to actively address the increasing use of standalone software in healthcare settings, often via technology platforms such as smart phones and the internet.

In particular, the updated manual clarifies that standalone software for patient monitoring may be classified as a medical device when the software influences the use of another existing device. The patient monitoring software in question – intended for use in intensive care wards – is an electronic medical record and clinical information system supporting bedside devices, allowing healthcare providers (HCPs) to remotely consult a patient’s status and review other standard or critical near real-time patient data. The software also enables HCPs to determine a specific action to be taken if the bedside device generates an alarm. The manual concludes that “if an alarm is noted on the system the users are instructed to interact with the bedside device, which would be considered to be influencing the use of the bedside device.”

Industry should consult the updated EU manual when determining whether newly developed (or existing) standalone software systems, such as medical apps, may be regulated as medical devices under EU legislation.
Additional Guidelines Related to Standalone Software

Other important guidelines on standalone software have also been issued by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from Australia, Brazil, Canada, China, the EU, Japan, Russia and the U.S., who are pushing for international clarification and convergence of medical device legislation. The IMDRF defines “software as a medical device” (SaMD) as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.”

IMDRF guidelines on standalone software include a 2013 guidance document setting out the key definitions of software as a medical device (link) and a 2014 document providing guidance on risk categorization (link). Earlier this month, the IMDRF issued a 2015 document providing guidance on the application of existing standardized and generally accepted quality management system (QMS) practices to SaMD (link).

If you have any questions regarding this Sidley Update or wish to discuss your company’s compliance with EU medical devices legislation in general, please contact the Sidley lawyer with whom you usually work, or

Maurits Lugard  
Partner  
+32.2.504.6417  
mlugard@sidley.com

Maarten Meulenbelt  
Partner  
+32.2.504.6467  
mmeulenbelt@sidley.com

Josefine Sommer  
Associate  
+32.2.504.6427  
josefine.sommer@sidley.com

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