When does software become a medical device?

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It is now easier than ever to monitor our physical condition. Not only can we measure our pulse during physical exercises, the number of steps and calories burned, but we have apps that also show the effect on our health. Some applications even collect information about our illnesses, the medication we take, as well as information about our allergies, on the basis of which adequate therapy or exercises are recommended.

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A major part of these monitoring devices is software which, from the legal point of view, can be recognized as a medical device (standalone software or Software as a Medical Device "SaMD"). For software manufacturers this can create new legal obligations.

SaMD as a medical device?

Estimates show that by the end of 2015 health&fitness applications for mobiles and other portable devices will have approximately half a million users. Even though many regulatory obligations have already been imposed on manufacturers, software companies are wrongly assuming that their products are not subject to any special legal regulations.

According to European Union Directive 2007/47/EC, a 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application (…).

The above definition clearly indicates that software can constitute an independent medical device. The definition also reflects the general rule that software constitutes a medical device – SaMD – if the manufacturer created it for one or more of the medical purposes described in the above definition, e.g. independent software used to improve the quality of radiological and ultrasound scans.

At the same time, software incorporated into a medical device should not be classified as an independent, separate medical device, but as an integral part of the existing device. In practice, application of this principle results in many interpretative complications, beginning with determination whether software in question is a medical device or a part of a different device. Also questionable is when software should be considered to be intended to be used for medical purposes.

Health prescribed by an application

Thanks to additional accessories or software installed on a computer or a smartphone, devices which are not medical devices are commonly used for medical purposes. It has been assessed that during the first quarter of 2014 there were approximately 100 000 health applications (mHealth apps) compatible with iOS or Android. Many standard mobile phones or tablets have not only basic applications, but also more advanced ones which are designed for chronically ill people (app. 31% of mHelath apps), for people interested in health and fitness (app. 28% mHealth apps) and even for doctors (14% mHealth apps).

Currently, no data is available as to how many of these applications have been properly registered as medical devices and which of them, despite paramedical features, cannot be classified in this group e.g. software used only to record patients' data. Because this issue raises more and more international doubts, people are trying to reach a consensus onflexible legal solutionsthat will allowfor a clear separationofSaMDand common software.

This will make it possible to developan adequate safety requirements for both categories. It goes without saying that software should be under stricter regulatory obligations if it is used for medical purposes.

Seeking a definition

The International Medical Device Regulators Forum (IMDRF), which is a voluntary assembly of regulations authorities from for example USA, EU, Canada, Japan and Brazil, is attempting to create a universal definition of SaMD, which would be the basis of national regulations, including EU legal regulations.

In December 2013, after public consultations, the IMDRF presented its basic proposal of the new definition ofSaMD, according to which SaMD should be treated as software to be used for medical purposes and which fulfils this purpose not being a part of a different medical device.

Despite numerous controversies and its imperfections, the definition will have considerable influence on future EU regulations regarding medical devices, which are still subject to intensive negotiations. An agreement on a unilateral approach to this issue in the USA and EU would be of major significance for importers, exporters and distributors of medical devices. Even though both the American FDA (Food and Drug Administration) and the EU Commission released guidelines on this matter, a number of issues require further clarification. This is evident, for instance, in the diversified practice on the qualification of software in medical and non-medical devices in EU Member States as borderline products.

Due to this fact, many countries have issued more detailed guidelines and regulations when software should be qualified as SaMD, for example the English MHRA (Medicines and Healthcare Products Regulatory Agency), which in March released short guidelines.

Despite these guidelines, companies which develop or distribute software used for medical purposes indicate that one of the main barriers to the development of this market is the lack of appropriate standards and transparency in the existing regulations.

Moreover, many mobile application developers do not know if regulatory requirements are applicable to their products, whereas, even at the design stage of software development, developers should produce it in a way that allows proper verification and validation (examples could be Med-Trace or MediSpice).

Analysis and verification

It is important to bear in mind that adopted procedures aim to protect users, i.e. patients and consumers, because their health should be the highest value when creating software used in SaMD, mHealth apps and training applications. These devices are enhanced each year with more and more advanced functions that should keep us in good physical condition.

In case of manufacturers and distributors of such software it is important, even at the early stages of software development, to analyze the legal status of the software or the entire device in terms of regulatory requirements and product liability. Breaches of regulatory requirements in Poland might result in fines, or even imprisonment, depending on the nature of the committed offense.

It should also be a red-flag for investors of health&fitness companies that future legal regulations might significantly raise operational costs of new product releases or increase the costs of current investments.