# eHealth, Innovation and Regulation

## The Medical Device Case

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# The new Medical Device Regulations

- **MDR - Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on **medical devices**, repealing Council Directives 90/385/EEC and 93/42/EEC

- **IVDMDR - Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on ***in vitro* diagnostic medical devices,** repealing Directive 98/79/EC and Commission Decision 2010/227/EU

# MDR
# The intent of the MDR is to support innovation

**Whereas: (1)**

A fundamental revision of the Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health **whilst supporting innovation**.

# MDR - Whereas: (19)

## Software can either be a medical device or not a medical device

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device**, qualifies as a medical device**, while,

Software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes **is not a medical device.** The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

# Classification of software that qualifies as a medical device

1. Software, which drives a device or influences the use of a device, shall fall within the same class as the device
2. Software that is independent of any other device shall be classified in its own right

# Classification Rule 11 - software

**Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes** is classified as **class IIa**, except if such decisions have an impact that may cause:

— death or an irreversible deterioration of a person's state of health, in which case it is in **class III**; or

— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.

**Software intended to monitor physiological processes** is classified as **class IIa**, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as **class IIb**.

All other software is classified as **class I**.

# Does classification Rule 11 (software) pose a business risk and innovation risk ?

- Rule 11 of the MDR implies that the majority of stand-alone software has to be declared as class IIa, IIb or III device.
- Only a very few exceptions might be declared as class I device.
- Consequently, **in most cases producers have to perform conformity assessment, involve notified bodies and establish a quality management system** which has to be certified.
- Most healthcare IT providers went for a class I classification in the past, i.e. for the lowest classification level, and the easiest to reach.
- **With the MDR rule 11, efforts and costs are expected to be multiplied** which will be challenging and difficult for small producers like application developers and SMEs
- **This may aggravate the development of medical software products** to an extent that small manufacturers can barely overcome the regulatory hurdles.

# 7 December 2017; the Court of Justice of the European Union (CJEU) issued its judgment in Case C-329/16

The CJEU held that software can be classified as a medical device under EU law **if the software has at least one functionality that allows the use of patient-specific data to assist the physician in prescribing or calculating the dosage for treating the underlying condition**.

It does not matter whether the software acts directly or indirectly on the human body.

The decisive factor is whether the software is specifically intended by the **manufacturer to be used for one or more medical objectives** specified in Article 1(2) of **Directive 93/42/EEC** (the Medical Devices Directive), including the diagnosis, prevention, monitoring, treatment or alleviation of disease.

# MEDDEV Guidelines

The CJEU decision validated the criteria set out in the specific MEDDEV for classification of software medical devices.

While the MEDDEV Guidelines are explicitly stated to be non-legally binding, industry and regulatory authorities may now rely on these to a greater extent for the purpose of assessing classification, but will the MEDDEV Guidelines continue to exist?

# Whether a software program constitutes a medical device may also be guided by reference to the Borderline Manual

On April 23 2018 the European Commission published Version 1.19 of the Manual on Borderline & Classification, following the release of Version 1.18 in December 2017

**NOTE:** the Manual refers to the Medical Device and IVD Directives, therefore it will be revised at the end of the European Regulations 2017/745 and 2017/746 relevant transition period.

# On the other side of the pond…

Sep 12, 2018

Apple Chief Operating Officer Jeff Williams, said today at an event in Cupertino that the company has received FDA clearance for both an atrial fibrillation-detecting algorithm and an ECG that will be built into the new Apple Watch Series 4

# US highlight

- Apple, Amazon, Google, Fitbit, etc…. are pushing technology
- FDA shows clear efforts to adapt to the pace of technology and to adjust to a risk-based approach for approval and use of such technology as medical device. Many such devices are “advisory” and not medical devices
- **June 2016:** FDA issued General Wellness: Policy for Low Risk Devices, a guidance intended to clarify whether fitness or consumer devices fall under the Agency device regulations
- **Dec 2016:** Congress signed the 21st Century Cures Act
  - Commitment to review FDA approval processes
- **Sep 2017:** FDA announced selected participants in its **pre-certification** program (Apple, Fitbit, Samsung, etc)
- **Oct 2017:** FDA issued revised guidance on the De Novo process

# Software, mobile technology, sensors and Real World Evidence (RWE)

- Section 3022 of the 21st Century America Cures Act, enacted in December 2016, directed FDA to develop a program to evaluate potential use of RWE to support approvals for **new drug indications**, as well as satisfy post-approval study requirements
- **On August 31, 2017**, FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) issued a guidance document describing situations in which they could accept RWE in support of regulatory decisions involving **medical devices.**

# RWE is “evidence derived from Real-World Data through the application of research methods.”

“Real world data” (or RWD), according to FDA, consists of information relating to patient health status or the delivery of health care such as,

- electronic health records (EHRs),
- insurance claims data,
- product or disease registries, or
- at-home patient monitoring devices,
- can also include environmental exposures and socio-economic factors.