Telemedicine: comparing EU and US application regulation

Alexis Gilroy, Cristiana Spontoni, Colleen Heisey and Indra Bhattacharya of Jones Day review the regulation of telemedicine applications in the EU and the US, and how medical device regulation underpins this.

Telemedicine ('TM') applications typically involve the collection, storage and/or transmission of data or health services using telecommunication services. In certain cases, the underlying software systems and the associated hardware may be regulated as medical devices.

Regulation of TM in the EU

The regulation of medical devices in the EU is governed by three key Medical Device Directives ('MDDs')[1], providing a harmonised framework. Although there are differences between Member States ('MS') in how these have been implemented into law, the core legislative framework set up under the MDDs provides that medical devices must conform with certain 'essential requirements.' These vary depending on the class and type of device, though broadly they seek to ensure that medical devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients or users. The EU regulatory framework is not prescriptive as to how compliance is demonstrated. Typically compliance with 'essential requirements' described in the EU Directives is demonstrated through compliance with harmonised technical standards, where these exist. Compliance with such standards provides a presumption of compliance with the applicable EU Directives' 'essential requirements.' Of interest is a public consultation launched by the European Commission ('EC') on 23 September 2015 on the technical standards that are needed to achieve the Digital Single Market, which was looking for stakeholders' input on the development of such standards in a number of fields, including specifically eHealth applications[2].

In the EU, similarly to the US, medical devices are divided into four distinct classes depending on risk assessment and characterisation. The European classes are Class I, Class IIa, Class IIb and Class III[3]. The classification of the medical device determines the assessment route(s) available to show compliance with the essential requirements, leading to a CE mark. A key feature of the European system is that medical devices are not subject to any pre-market authorisation by a government regulatory authority (unlike in the US) and the more limited conformity procedures often allow medical devices to reach the market more quickly than in other jurisdictions. MS nominate a 'Competent Authority' (government agency) to monitor and ensure compliance with the provisions of the MDDs, and each in turn designates 'Notified Bodies' ('NBs') (private entities contracted by industry) to carry out the relevant assessment procedures. The procedure for conformity assessment is risk-based, taking into account the classification of the medical device, the intended clinical mode of use and the nature and characteristics of the device; class I devices are not externally assessed by NBs but are self-certified by the manufacturer.

Under the MDDs a 'medical device' is broadly defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(iii) investigation, replacement or modification of the anatomy or of a physiological process; or

(iv) control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

There are a number of aspects of TM systems that may fall within this definition if the relevant product or service is intended to have a medical purpose (as defined above). This is assessed by having regard for both the expressed intention of the manufacturer (i.e. by looking at labelling, instructions and/or promotional materials) as well as the surrounding circumstances and context in which the product or service is made available.

Stand-alone software has been explicitly regulated as a medical device in the EU since 2007, when a revision of the MDDs was introduced through Directive 2007/47/EC[4] to ensure 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, is a medical device.'[5] At the time it was also specified that software for general purposes when used in a healthcare setting is not a medical device.

Diagnosis and therapy software

The most obvious example is stand-alone software specifically designed for use in formal medical diagnosis and/or therapy directed at individual patients (e.g., software systems that enable remote presentation of heart rate). These are likely regulated as either Class IIa or IIb medical devices, requiring oversight from a designated NB. Similarly, stand-alone picture archiving and communication systems ('PACS') that are intended by the manufacturer for viewing, archiving and transmitting medical images remotely in the context of direct diagnosis will be usually classed as IIa devices though where these devices either drive or influence the use of a source device they will be classified in the same class as the source device[6].

Communications software

Communications software (and the associated IT and hardware infrastructure) used with telemedicine systems will usually be regulated as medical devices if they facilitate the monitoring and/or delivery of healthcare services remotely. For instance, virtual reality technology and hardware that is designed to be used to conduct surgical procedures from a remote location will most likely be regulated as Class IIb or Class III devices. On the other hand, systems that are more administrative in nature (e.g. video appointment software, virtual patient management systems) are unlikely to be classed as medical devices.

Mobile 'apps'

Even in more consumer-focused settings applications may be regulated as medical devices if they are clearly intended to be used for a medical purpose. This is a tricky area however because the assessment may not always be straightforward given these products often sit on the borderline between a medical and wellbeing/leisure purpose (e.g. an app that provides heart rate monitoring with remote data processing functions). The UK's Competent Authority (the 'MHRA') recently issued some guidance[7] suggesting that certain words defining an app's function (e.g. amplify, analysis, calculate, detect, diagnose) may be indicative of a medical rather than a wellbeing/leisure purpose, but acknowledged that in the context of telehealth the difference between social care, wellbeing and health can be blurred. In the meantime, until there is further clarity from the regulatory authorities, manufacturers can take some comfort in the fact that most consumer apps, even if they are regulated, are likely to be Class I devices and therefore can be self-certified (without the need to involve any NBs).

There is significant market interest in telemedicine applications' potential. However, there is still a great deal of uncertainty regarding how the EU and US medical devices regulatory regimes will deal with the associated technologies and applications

Telemedicine in the US

Mobile medical apps ('MM Apps') and medical device data systems ('MDDS') are considered medical devices regulated by the US Food and Drug Administration ('FDA'). Under the Federal Food, Drug, and Cosmetic Act, a 'device' is defined in pertinent part as 'an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article' that is 'intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man' or 'intended to affect the structure or any function of the body of man' and 'which does not achieve its primary intended purpose through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.'[8] The regulation of MM Apps and MDDS conform to the FDA's risk-based regulatory regime, the requirements of which may include establishment registration and medical device listing, labelling, investigational device exemption requirements, pre-market submission for approval or clearance, Quality System regulation, medical device reporting, correcting problems, and reporting corrections.

Mobile medical apps

The FDA cites industry estimates that 'by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications.'[9] More than a few of these apps will qualify and be regulated by the FDA as MM Apps, a device either intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device. The FDA released and finalised its thoughts on how MM Apps will be regulated via a document aligned with the Agency's risk-based approach[10]. Where regulatory requirements apply, manufacturers will be required to follow appropriate rules, namely general controls and potentially, specific controls, pre-market notification, and pre-market approval.

The FDA intends to regulate only those MM Apps whose functionality could pose a risk to patient safety if the app does not function as intended. The FDA is focusing oversight on those apps: that connect a medical device to control it, actively monitor patients, or analyse medical data; that transform the mobile platform into a medical device with the use of attachments or inclusion of functionalities similar to those of currently regulated medical

devices; and that perform patient specific analyses, diagnosis, or treatment recommendations.

The FDA has determined the relative risk of certain types of apps as being appropriately low as to require no oversight. The FDA extends enforcement discretion to patient-facing MM Apps that help self-management of a disease/condition generally or provide simple tools to organise and track health information. For healthcare providers, it includes those automating simple tasks or supporting patient/provider interaction with personal health records or electronic health record systems[11]. The FDA does not intend to enforce regulatory requirements for mobile apps that transfer, store, convert format, and display medical device data in its original format from a medical device, as defined by the MDDS regulation.

Apps the FDA does not consider to be medical devices include those intended to provide access to electronic copies of certain reference material; those for use as educational tools for medical training; for general patient education; to automate general healthcare office operations; and general purpose products.

Medical device data systems

Products that contain or consist of computer and/or software components are also subject to device regulation if they meet the definition of a device, including MDDS. MDDS is a device intended to, without controlling or altering the functions or parameters of any connected devices, perform: the electronic transfer, storage, or display of medical device data, and/or the electronic conversion of medical device data from one format to another format according to a preset specification[12]. An MDDS does not modify the data it handles and does not control the functions or parameters of any connected medical device. The definition of MDDS does not include devices intended for active patient monitoring or those devices that are to be relied upon in deciding to take immediate clinical action, where the circumstances require a timely response.

Historically, the FDA has regulated MDDS as high-risk, Class III, but in February 2011, the Agency reclassified MDDS to low-risk, Class I, subject to general controls, determining that these technologies pose a low risk to the public. Consequently, the FDA decided it would not enforce compliance with regulatory controls that apply to MDDS devices, medical image storage devices, and medical image communication devices, including registration and listing, pre-market review, post-market reporting, and quality system regulation for manufacturers of these devices[13].

Conclusion

There is significant market interest in TM applications' potential. However, there is still a great deal of uncertainty regarding how the EU and US medical devices regulatory regimes will deal with the associated technologies and applications. Both regimes appear to be mostly taking a sensible risk-based approach, though this may change as adoption of technology develops. There are a number of important developments underway that could dramatically change the regulatory landscape. The EC is presently undertaking a review of mHealth technologies including a focus on TM products and services. The existing European MDD regime is also in the process of being completely revamped and a radically new regulatory system is expected to come into effect within the next four to five years. The FDA is continuing to evaluate the evolving field and application of its risk-based scheme.

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1. (i) Directive 90/385/EEC regarding active implantable medical devices, (ii) Directive 93/42/EEC regarding medical devices, and (iii) Directive 98/79/EC regarding in vitro diagnostic medical devices.
2. http://ec.europa.eu/digital-agenda/en/news/have-your-say-standards-help-achieve-digital-single-market
3. The classification depends on criteria such as the duration of contact with the body and the degree of invasiveness.
4. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.
5. See Recital 6 of Directive 2007/47/EC.
6. See for example, EC Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, v 1.16 (2014).
7. https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps
8. FDCA §201(h) / 21 U.S.C. §321(h).
9. FDA, Mobile Medical Applications. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm
10. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff; US Food and Drug Administration (9 February 2015).
11. The MM App policy, however, does not apply to apps that function as an electronic health record system or personal health record system.
12. 21 C.F.R. § 880.6310.
13. Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff. US Food and Drug Administration (5 February 2015).