Mobile medical apps guidance: what's good for the US is good for the EU

Bradley Merrill Thompson and ***Erik Vollebregt*** argue that draft guidance from the US Food and Drug Administration on mobile medical applications could apply in the EU too.

On 21 July, the US Food and Drug Administration released draft guidance on mobile medical applications[1,2], a document we think has great significance for the regulation of the EU eHealth and medical device markets, even while in draft form. If the FDA revises the guidance based on the substantial comments it is receiving from industry, the importance of the guidance will only increase. In our opinion, because of the underlying similarities in the basic legal framework in the two jurisdictions, this FDA guidance could be used more or less without changes in the EU under the Medical Devices Directive[3].

There are several reasons this document is so significant for regulation of eHealth and medical devices markets in the EU.

Firstly, as we have indicated, the similarities in the basic legal framework in the US and the EU with regard to the scope of software and hardware regulation are substantially similar, so any guidance in one of those jurisdictions is likely to be useful in the other.

Secondly, although the MDD and associated guidance address software in very general terms, EU regulation is behind the US in terms of the sophistication and level of detail provided. The different EU stakeholders and regulators cannot seem to agree on guidance, either as to substance or form, after the publication of the so-called "Swedish report" – proposals for guidelines on the classification of software based information systems used in health care from Sweden's Medical Products Agency – in June 2009[4,5]. In the meantime, the industry, and in particular the clinical institutions in the EU, are having difficulties understanding how apps, websites and software with diagnostic and/or therapeutic functionality are regulated[6].

Thirdly, because the reasoning of the FDA guidance fits so well into the EU regulatory system, medical technology and software companies can rely on the same software and devices being regulated as medical devices. Of course, the underlying authorisation process differs significantly between the EU and the US, but guidance as to the scope of regulation that seems to work under both systems is a big step forwards for the market.

Scope of software regulated

The FDA proposes that the guidance be applicable to mobile medical applications or "mobile medical apps", defined as:

- a software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server; *and*
- has an intended use within the scope of the concept of medical "device" as regulated by the FDA; *and*
  - are used as an accessory to a regulated medical device; *or*
  - transforms a mobile platform into a regulated medical device.

Although the word "app" is misleading here – because that seems to refer to software that is stored and run locally – it is quite clear that web applications are also covered by the definition. The above points work exactly the same in the EU: the intended purpose of the app determines whether it is regulated under the MDD. Accessories are regulated in the EU as well, even though the definition of accessory may differ somewhat.

Examples of regulated applications include:

- mobile apps that are an extension of one or more medical device(s) by connecting to such device(s) for purposes of controlling the device(s), or displaying, storing, analysing or transmitting patient-specific medical device data; or
- mobile apps that transform the mobile platform into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices; or
- mobile apps that allow the user to input patient-specific information and – using formulae or processing algorithms – output a patient-specific result, diagnosis or treatment recommendation to be used in clinical practice or to assist in making clinical decisions (emphasis added).

The FDA plans to address in a separate issuance mobile medical apps intended to analyse, process or interpret medical data (electronically collected or manually entered). The FDA held a hearing on that topic in early September[7], and seems to be moving along quite quickly towards a draft guidance. This category of devices would fall as well under the EU definition of medical devices with diagnostic functionality and be regulated accordingly.

Excluded from regulation are mobile apps that:

- are electronic "copies" of medical textbooks, teaching aids or reference materials, or are solely used to provide clinicians with training or reinforce training previously received. These types of apps do not contain any patient-specific information, but could show examples for a specific medical specialty. In EU regulation terms, these devices quite clearly do not achieve a therapeutic or diagnostic effect "in or on the human body" as required by the definition of "medical device" under the MDD;
- are solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness, provided that they are not intended for curing, treating, seeking treatment for mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition. This outcome would be largely similar under EU law as there is no intended therapeutic or diagnostic use except that the EU definition also covers "investigation [...] of the anatomy or of a physiological process" which makes these apps borderline cases under EU law;
- only automate general office operations with functionalities that include billing, inventory, appointments or insurance transactions. These are also excluded under the MDD as general purpose software[8] or as not having an intended use within the scope of the MDD;
- are generic aids that assist users but are not commercially marketed for a specific medical indication, such as recording audio, note-taking, replaying audio with amplification, and other similar functionalities. These are currently also excluded under the MDD; and
- perform the functionality of an electronic health record system or personal health record system. These are also excluded under the MDD.

Manufacturer

A mobile medical device manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application in whole or from multiple software components. Examples of mobile medical device manufacturers include any person or entity that:

1. Creates, designs, develops, labels, re-labels, remanufactures, modifies or creates a

software system from multiple components.
2. Provides mobile medical app functionality through a "web service" or "web support" for use on a mobile platform.
3. Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution.
4. Creates a mobile medical app intended to be used on a mobile platform, or that manufactures a mobile app to be supported by hardware attachments to the mobile platform with a device intended use. All of this fits perfectly in the definition of manufacturer under the MDD, defined as "the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party". An important point is that the FDA urges manufacturers of applications that do not meet the definition of "device" still to apply a quality system to the design and development processes.

A standard that in our view would work for the EU is EN 62304[9] on life cycle requirements for medical devices software harmonised under the MDD.

Distributors

A very important final point in the draft guidance is that the FDA expects distributors of mobile medical apps who may or may not be a platform or service provider to co-operate with manufacturers in conducting corrections and removal actions. The agency requires medical app manufacturers to make timely reports of corrections and removals made to reduce a health risk or remedy a violation of the Food, Drug & Cosmetics Act that presents a health risk, and to keep records regarding other corrections and removals. In EU wording: the manufacturer must exercise control over its supply chain and be able to implement corrective action through its supply chain, as is currently the case under the MDD, while the supply chain is expected to co-operate. This latter requirement is not laid down in the MDD yet, although developments in the new regulatory framework for EU directives relating to CE-marked products lead us to expect that this will be included in the planned recast of the MDD[10].

This is a very important point because, in our experience, manufacturers distributing apps via larger stores will have no control whatsoever over these stores, like the iTunes Store or the Android Market. They will have very limited options to implement field safety corrective action (in US wording: recall) in case of serious issues. If the FDA and the EU authorities are serious on safety in this respect, they should require design functionality that gives the manufacturer sufficient reach through to the user (eg by means of push messages to discontinue use or to upgrade the app to a new version), but also make it clear to the middle men that they have a duty to co-operate as they may be facilitating illegal/unsafe medical devices. In the EU, that would mean that the store would, for example, lose its "mere intermediary" immunity under the e-Commerce directive[11].

Conclusion

A lot more can be said about this subject, like how to implement in practice all the consequences of a mobile app being regulated as a medical device in practice, but we will leave it at this for the moment. In the US, as we write this article, industry is drafting substantial comments on the FDA proposal to identify additional areas where clarity is needed. Even so, this draft guidance should be welcomed on both sides of the Atlantic.

While we believe the final guidance in the US may change substantially to address the additional questions raised by industry, we believe that the EU authorities should use the US process to their advantage as a basis for the much-needed and due step in the clarification of EU regulation of mobile medical apps under the MDD. We hope the EU regulatory authorities will study not only the FDA draft but the comments industry is submitting. Further, companies faced with the question of whether or not their app is regulated under EU medical device law can use the guidance, and especially the final guidance, as a rule of thumb to determine whether it is likely that their app would be regulated under the MDD.

References

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