Should apps and other innovative software be CE marked as devices? The legal view

The trend towards IT-enabled healthcare is expected to continue as the adoption and use of these technologies rises steadily. Going forward, a critical question for companies will be how they can evolve their business model to capitalize on this digital revolution.

Given the complexity of the issues involved in assessing the regulatory borderline between general software and medical devices and the limited guidance currently available, companies should take an open-minded and pragmatic approach, but still exercise caution when analyzing whether an app qualifies or not as a medical device.

We have seen a significant rise in the number of companies approaching our law firm’s IP regulatory department for advice on the qualification of software, and specifically apps. Typically, manufacturers require a legal opinion assessing whether their app may qualify as a medical device under EU medical devices legislation and must therefore bear the CE marking.

Pharma and medical device companies, in particular, are keen to establish themselves in the eHealth market. It is important to note that the pharma or medical device company itself which places the software on the market would bear legal responsibility as the “manufacturer” for compliance with the medical device regulatory framework even when they have contracted a third party to develop the software.

Regulating apps as a medical device
Apps intended companies placing them on the market to be used specifically for diagnostic and/or therapeutic purposes (i.e. for one of the medical purposes listed in the four indents to the definition in Directive 93/42/EEC as amended) are regarded as medical devices in their own right.

A key aspect of product qualification is therefore whether the app is intended by its manufacturer to be used, for example, specifically for diagnosis, prevention, monitoring and/or treatment of disease, irrespective of whether it is used generally in a hospital or other clinical environment. It is therefore essential to look at the intended purpose and the technical functionality of the app.

Of course, software which qualifies as a medical device and which is a system intended to be used for the purpose of providing in vitro examination of a specimen derived from a human body will be treated as an in vitro diagnostic.

Grey areas
Whilst EU medical devices legislation states that standalone software can qualify as a medical device or an IVD (or as an accessory to either), it does not clearly stipulate when this happens.

The European Commission attempted to address this ‘grey area’ by publishing guidance in January 2012, known as MEDDEV 2.1/6. The MEDDEV is intended to assist manufacturers and regulators in determining whether standalone software should qualify as a medical device or an IVD. However, questions still remain.

Firstly, the guidance is not legally binding although it is likely to be persuasive for the courts. Secondly, as the EU medical devices legislation does not have direct effect, there may be country-to-country variations in its implementation into national law and differences in the approach of the local regulators with regard to the qualification of software. For example, some countries appear to embrace a risk-based approach despite the fact that the risk related to a malfunction of the software is in itself not a criterion for qualification as a medical device. From our experience, the UK’s Medicines and Healthcare products Regulatory Agency takes a pragmatic approach when considering the qualification of apps.

Ultimately, only the Court of Justice of the European Union (CJEU) can decide definitively whether a specific product falls within the EU medical devices legislation or not.
It is also important to note that, for borderline products, regulators may be influenced by the determinations in respect of any similar software applications made by Member State regulators and also regulators in jurisdictions outside of the European Economic Area (EEA), like the US. For this reason, companies are advised to take a global approach when developing eHealth strategies.

With the rise of software being developed specifically for use in the healthcare environment, companies need to focus on these medical device qualification issues and take all of these factors into consideration.

The pace of technical advancement is moving faster than the legislation and guidance in this area and so assessment of these issues is not straightforward. Of interest to companies, we are also aware that the MHRA plans to publish an FAQ document addressing software qualification issues, which should be available by the Autumn.

**Examples are helpful but not exhaustive**

The MEDDEV discusses general principles that apply when considering the qualification of software and contextualizes this guidance by providing some illustrative examples. Whilst helpful, these examples are not exhaustive.

In some cases, it is clear when software has an intended medical purpose. Relevant factors are likely to include whether information is made available by the software to clinicians, not just for reference, but for driving or influencing treatment or diagnosis. In other cases, the lack of a medical purpose will be obvious.

However, not all examples are this clear cut; it is the borderline uses that are most tricky to analyze, for example when the app is intended to deliver some form of patient monitoring. Neither the legislation nor the MEDDEV clearly define the term ‘monitoring’; our interpretation is that there must be some form of direct monitoring (e.g. monitoring of a patient’s specific clinical signs, like blood pressure) for the app to qualify as a medical device. Indirect forms of monitoring like trend analysis would not necessarily mean the app qualifies as a medical device.

The MEDDEV draws a distinction between software that simply stores, archives or communicates data, for example, and more sophisticated applications. It is important to analyze whether the app is carrying out any analysis, calculations, enhancements or interpretations of captured patient data for a therapeutic purpose. If the app carries out an analysis that will be relied upon by the clinician in making a diagnosis or determining a treatment for a patient, then the app will certainly qualify as a medical device.

By way of example, a Body Mass Index calculator which takes a patient’s height and weight and produces a score according to a simple formula is in our view not likely to qualify as a medical device. However, a dosage calculator that produces a recommended medicine dosage (i.e. for treatment of a disease) based upon inputted patient details would fall within the medical devices legislation.

We are seeing more pharma and medical device companies wishing to provide apps to clinicians (often free of charge) which are intended to assist them during their consultations with patients. The major objective of these apps is to improve patient care and encourage best practice. This could be by way of enabling a quick diagnosis through to effective prescribing (i.e. there is an intended medical purpose), or simply by providing educational materials on a range of lifestyle topics aimed to encourage change (e.g. giving up smoking) which do not necessarily have a medical purpose.

Depending on the app, it may help to increase awareness of the company amongst the general public or strengthen relationships with healthcare providers provided that such offerings are not given as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine or device.

**Legal judgment in multi-purpose case**

Some standalone software may break down into a significant number of applications for the user where each of these applications is correlated with a module. Some of these modules may have a medical purpose, whilst others not. This raises the issue as to whether the whole product can be CE marked when not all applications have a medical purpose?

The MEDDEV states that it is the manufacturer’s obligation to identify and assess the different modules to determine which ones fall within the scope of the medical devices legislation.

Interestingly, this guidance appears to contrast with the recent Advocate General’s Opinion in Brain Products GmbH v BioSemi VOF and Others (Case C-219/11), which was endorsed by the CJEU. In this case, a competitor initiated legal action against BioSemi, which markets a product called ‘ActiveTwo’. ActiveTwo is a modular system capable of recording electrical signals from the human body and, more specifically, from the brain, heart and muscles. The Advocate General stated that it is “precisely the intrinsically flexible nature of the ActiveTwo system that would make it impossible to make that system subject to certification as a medical device”.

**Customization**

What about user customization? If a manufacturer does not CE mark its software but permits the end user to customize the software potentially for specific medical purpose uses, such off-label use increases the risk that the competent authorities may infer the company is in fact marketing (i.e. intending) the product for use for medical purposes. So, caution should be exercised when giving instructions for the development of apps.

**Benefits to CE marking apps**

If a product is caught by the medical devices legislation, the next step for the company to consider is the regulatory requirements that apply for CE marking the software. The process ultimately depends on how the product is classified.

Whist there are some drawbacks with qualification as a medical device (including the time and money that must be invested by companies before they can legally CE mark the software), there are many benefits.

The CE marking acts in effect as the passport that authorizes the device to be placed on the market and to circulate freely within the EEA.
currently giving access to 31 countries. Qualification as a medical device also enables the manufacturer to make stronger claims in the product labeling, packaging, instructions for use and other promotional materials.

Whilst an individual assessment must be made, most apps that qualify as medical devices are likely to fall within Class I - in which case the conformity assessment procedure is relatively straightforward. For Class I devices, the manufacturer normally only has to self-certify compliance with the Essential Requirements before it can register the device and place it on the market (rather than needing to obtain certification from a notified body). The exception to this is where Class I devices have a measuring function and/or are sterile and then the notified body needs to be involved in checking these aspects.

On the other hand, some companies specifically want to understand what changes can be made to the design and use of an app to reduce or eliminate the likelihood of device qualification.

Whatever decision a company ultimately takes with regard to the positioning of its software, it is necessary to ensure consistency with all information relating to the product including the software licence terms. In particular, if a company legally places an app on the market as general software, the company should avoid marketing the app in connection with a medical purpose. Sales staff should also be trained to ensure they do not market the product for purposes outside of its stated restrictions.

Revision of the medical devices legislation

In addition to the current situation, manufacturers need to consider the impact of the European Commission’s proposal to revise the existing EU Medical Devices Directives 90/385/EEC and 93/42/EEC, both as amended, into an EU Regulation which specifically targets the regulation of software.

It is also worth mentioning that the IVD Directive 98/79/EC, as amended, is separately being revised as an EU Regulation with the European Commission’s proposal explicitly mentioning ‘software’ in the definition of an IVD.

Once finalized, these Regulations will be directly applicable in all EU Member States. Of particular note, the draft EU Medical Devices Regulation includes a revised definition of a ‘medical device’ which arguably broadens the number of software products that may fall within its scope. Annex I, section 14, of the draft Regulation also sets out new Essential Requirements for software (both incorporated and standalone) regarding safety and performance aspects.

The European Parliament is expected to vote on amendments to the proposals in the Autumn. The optimistic deadline for completion of the revisions and adoption of the Regulations is May 2014, but even if this happens, the majority of the provisions would not apply until three years after the Regulations enter into force. Companies intending to market apps should therefore keep a firm eye on these developments.

How widespread is eHealth and what is the outlook?

The term ‘eHealth’ is very broad. It includes information, communication and bio-medical technologies, tools and services for health. Examples include electronic health records, health information networks, prescription management systems, telemedicine services and many other mobile and internet based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management.

It is true to say that eHealth is at a relatively early stage in its development. Whilst figures vary, a recent report from MarketsandMarkets estimates that the global healthcare IT market could be worth up to $56.7 billion by 2017 up from $40.4 billion in 2012. It is thought that the US market may comprise close to 50% of this eHealth market due to the relatively high existing eHealth adoption and the fact that government funding is being focused in this area. Europe and the BRIC countries comprise the largest secondary markets with relatively less spending in developing countries.

So why have we seen a rise in eHealth over the past few years? With life expectancy continuing to grow, health services are under increasing pressure to deliver treatment options in a more cost effective way and to focus on disease prevention. This is coupled with the fact that we live in a more knowledge driven society and patients want to have more control over their own health options. eHealth is increasingly seen as a way to achieve these objectives by lowering costs, providing faster/instantaneous access to information and advice with less manual intervention, facilitating patient mobility and safety, and supporting a shift from hospital care to prevention and primary care.

Exploiting eHealth opportunities

eHealth solutions have a multitude of uses. For example, they can facilitate (i) interaction between patients and healthcare providers, (ii) transmission of data between hospitals and other institutions, and (iii) communication amongst patients themselves and/or between healthcare professionals. An example is in the area of diabetes with the use of monitoring equipment linked with mobile devices to provide real-time analysis of a patient’s insulin requirements.

As described in this article, one area of eHealth that is undergoing a particular boom is ‘mHealth’, a term used for the provision of healthcare services supported by mobile devices. Mobile apps are a key example. There are a number of reasons for the success of mHealth products and services. Mobile phones are ubiquitous, even in developing countries. The increased sophistication of smartphones and their functionality and processing capabilities also means they have increased potential to be used for mHealth purposes. Mobile phone technology is particularly useful for providing diagnostic and treatment support, remote monitoring, public health education and training for healthcare providers.

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This article was published by Clinica Medtech Intelligence on its website, www.clinica.co.uk, on 19 July 2013.