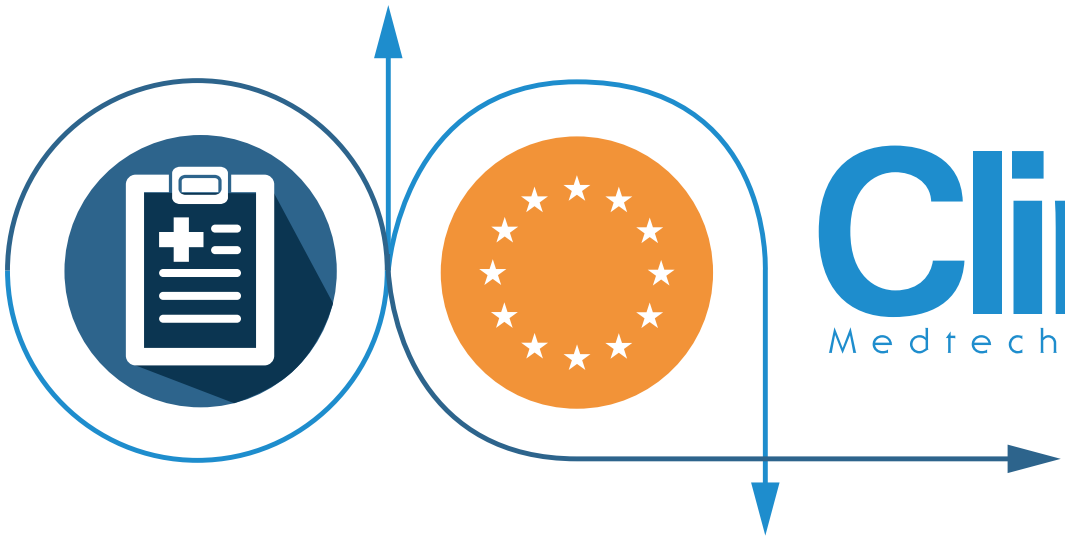

Clinica

Medtech Intelligence

The leading source on the medical devices and diagnostics industries

Clinica provides you with up to the minute coverage and opinion on company, product, market and regulatory developments as well as market size, growth and sales forecasts.

www.clinica.co.uk

Clinica
Medtech Intelligence

EU Commission's mHealth Code Nears Completion – But Will It Be A Success?

by Amanda Maxwell, 14 December 2015

DG CONNECT, the European Commission's department of communications networks, content and technology, has been working on an mHealth code, with the view to completing it by the end of 2016. Amanda Maxwell spoke with Erik Vollebregt, partner at Axon Lawyers and expert on mHealth matters, to find out more about the aim of the code and what it will mean for the medtech industry

• • •

Within the medical and well-being space, there is a plethora of apps that are being developed as well as already out on in the market and with this is the growing concern these apps could mislead people regarding their medical status, and encourage behaviour that could harm them.

Not surprisingly, there has been a call for some form of regulation. But the document that will be coming from the European Commission that addresses this issue may seem surprisingly narrow in focus for some, since the mHealth code looks set to address mainly personal health data issues.

It looks unlikely that there will be a bespoke regulation for medical device-type apps – or at least nothing imminent looks to be on the horizon, as had been hoped by some. Instead, Europe's forthcoming new medical device regulations look set to continue providing the framework for these products.


Erik Vollebregt

Clinica caught up with Erik Vollebregt, lawyer at Axon who specialises in mHealth and is involved in stakeholder comments on the code, to find out what has happened since the latest update after the eHealth Week 2015 organized earlier this year. Vollebregt explained the context of the code as well as its latest status.

Clinica: *Why has DG Connect developed an mHealth code?*

Erik Vollebregt: It is an action stemming from the Green Paper on mHealth, intended to increase confidence in the market at end-user level. Lack of trust at end-user level was one of the outcomes of the consultation, so DG Connect decided to remedy that with a code.

These trust issues mainly concerned personal health data collected and processed by the apps, so the code is data protection-oriented.

Clinica: *What players within healthcare are the code aimed at? And who has been involved in drafting and commenting on the code.*

EV: The code is aimed at SMEs that develop and market mHealth apps. DG Connect organized an elaborate stakeholder consultation and involvement in the process to ensure that this code has wide support and that everyone interested had an opportunity to contribute and make their views known.

Clinica: *Why a code and not a law? What impact will a code have?*

EV: For a number of reasons. When the Green Paper on mHealth was published, the Medical Devices Regulation proposal was already underway so the Commission was not going to propose something additional in that field.

Also, the General Data Protection Regulation (GDPR) proposal was underway, so the Commission was not going to propose additional legislation for mHealth in that field either.

The impact of the code will be to offer a pan-EU instrument with which companies can comply and which offers clear data protection rules in the whole EU. This would simplify matters considerably as data protection requirements can vary considerably from member state to member state.

Clinica: *When should the code be operational?*

EV: That is still not certain, but the code is close to finalization. The current planning is Q2 2016 for the code to be finished.

Clinica: *What will the impact be on manufacturers? And on the marketplace?*

EV: Adherence to the code will be optional so I expect that - depending on the success of the code - there will be a shift in the marketplace between compliant and non-compliant parties.

But since the code only concerns compliance with data protection law, I can also imagine that there will be parties that do not see the added value except as an advertising opportunity. The governance and enforcement mechanism has not been decided on yet, and that will also determine the impact. A code that has no enforcement attached to it may be less successful as a result of free riders that advertise compliance without possibility for end users or competitors to complain.

Clinica: *How is a distinction being made between lifestyle apps and medical devices? And what are the distinct proposals for each group?*

EV: There is no such distinction in the code because that difference is not relevant to data protection law.

The difference between personal data concerning health and 'other' personal data is a similar thing which is addressed in the code.

This distinction is a problematic one because of the not-so-clear guidance that the Article 29 Working Party recently published and the recent decision of the Dutch DPA (data protection agency). Here, the DPA found, in a case against Nike about the Fuel platform, that pure sports performance data constitutes personal data concerning health, if it is possible to draw conclusions about the data subject's health from them.

Clinica: *Is there still talk of a bespoke regulation for medical device type apps?*

EV: No, not that I know. They will be covered under the Medical Device Regulation and IVD Regulation, hopefully with an updated version of the MEDDEV on standalone software. In the meantime the Commission's Manual on Borderline and Classification will also continue to list new borderline cases of apps.

Clinica: *What does the code say on clinical evidence?*

EV: Nothing, because clinical evidence is not relevant to personal data legislation.

Clinica: *Will there be any guidance in meeting the code's proposals?*

EV: There is a lot of guidance hard-wired into the code. The code is set up as an easy-to-read document that gives a how-to guide for privacy law compliance. It explains data protection requirements in quite some detail and has a model Privacy Impact Assessment and a model consent statement included, for example.

Clinica: *What is the biggest advantage of having such a code, and what are the biggest disadvantage, and for whom?*

EV: The biggest advantage is that it offers an easy to understand summary of obligations in the field of data protection legislation.

The biggest disadvantage is that SMEs may think that these are the only obligations that apply to an mHealth app, which is not the case. For example, they may think that clinical evidence is not needed for medical apps that are medical devices. There is however, among other things, medical devices law, advertising law and e-commerce law to comply with.

Clinica: *Do you have any additional important observations?*

EV: The goal of the Commission is to have the code blessed by the Article 29 Working Party under the current Data Protection Directive and subsequently under the GDPR, so compliance with that code would constitute de facto compliance with data protection law - which would make the code important and contribute significantly to its success.

But the track record of such codes shows that problems can arise: the C-SIG cloud providers' code was also supposed to be blessed this way and that process started at the beginning of 2014 and is still not finished.

Some of the observations that the Article 29 WP had regarding that code as reasons not to bless it also apply to the mHealth code- notably the lack of a transitional mechanism towards the GDPR when that enters into force and a lack of a clear user rights paragraph that addresses practicalities such as data portability.

So it may be that the code has to exist without Article 29 WP blessing for some time at the least. And this could impact its success.