mHealth regulation in the EU: take the NO out of innovation!

Erik Vollebregt, Founding Partner and EU legal medical technology specialist of boutique life sciences firm Axon Lawyers, explains why he thinks the EU is hindering innovation in the mHealth space and the issues faced by his clients.

If you spend a lot of time with companies that are trying to figure out mHealth regulation in the EU, you develop a bit of skewed view on the legal and regulatory reality.

Of course you will have seen the positive spin that comes out of DG CNECT, which is doing its best to stimulate innovative start-ups in the mHealth space with all the best of intentions. On the other hand, you will also have seen DG SANCO dragging its heels on the Green Paper on Health and Wellness and have seen the data protection revision discussion spearheaded by DG JUSTICE go literally all over the place. Incoherent policies as a result of different DGs going different directions on policy is not new, but the faster economic developments go, the more harmful the impacts on developments are.

The European Court has just decided that there is no internal market for medical devices by confirming that every Member State can decide for itself if a product is a medical device or not – and that the scientific support for that can differ between Member States.

And then we have the revision processes of the medical devices directives and the general data protection regulation, both of which have severely freaked out the companies that have resources to comply with the new rules. The companies that are too small to follow the discussion have no idea what they can expect.

These are just some of the worrying things that make me conceive a title like this. I hope I do not offend anyone, but the EU is severely hampering innovation in the mHealth space by putting the 'no' in innovation in the mHealth space. This makes innovative companies move to other places.

Let me describe some of the things my clients run into in practice, and decide for yourself what you think.

No internal market for medical devices

Recently, in the Lycocentre case, the EU Court had to decide on the question of whether each Member State had the authority to decide that a particular product is a medical device or something else. You would think that it is really convenient that if you have a directive that provides for free circulation of a CE marked medical device, not each and every Member State can second guess another Member State's or notified body's finding of whether the software concerned is a medical device. The EU Court grudgingly came to the conclusion that, "None the less, as Union law currently stands, until harmonisation of the measures necessary to ensure the protection of health is more complete, it will be difficult to avoid the existence of differences in the classification of products as between Member States".[1] You can practically hear the judge grit his teeth in the language used. But what is more, "asymmetries in scientific information, new scientific developments and differing assessments of risks to human health and the desired level of protection can explain why different decisions are taken by the competent authorities of two Member States as regards the classification of a product."[2]

In other words: there is no central authority to qualify medical devices, science can differ and authorities can have different policies as to what they consider application of science to products for regulatory purposes and they are allowed to differ in opinion. This case puts a precise finger on the sore spot of the role of science in the qualification of medical products and the EU's paradoxical way of dealing with it in the light of division of competence between the EU and the Member States. On the one hand we all want the best state of the art clinical substantiation for medical devices to be fully scientific and we assume that science leads to the same conclusions everywhere. Actually, that is what the EU market access mechanisms for medical devices and medicinal products are based on. In a discussion I recently had with another expert we agreed that if you take this to its logical endpoint, gravity could go up in one Member State and down in another and that's OK for the EU Court because the law does not say it should pull towards the centre of the earth everywhere and Member States are not willing to agree to that when it does not suit their purposes. That, I think, is a very bad way to deal with products that we would like to be as much scientific evidence based as possible. That is basically impossible if you can't rely on underlying science being universal and Member States to be willing to give it their best scientific effort to conform to scientific state of the art.

Now you would probably think this kind of thing would be fixed in the currently pending medical devices and IVD regulation. Not quite. The issue is addressed somewhat by attributing the Commission with the power to propose implementing acts to 'determine whether or not a specific product, or category or

group of products, including borderline products, falls within the definitions of 'medical device' or 'accessory to a medical device".[3] But these implementing acts will be political instruments as they will need Parliament and Council approval, and will likely take a lot of time to be adopted. Furthermore, as case law currently seems to stand, companies will not be able to appeal them[4].

eLabelling

If you explain to someone outside the field of EU medical devices law that there is a rule that requires that software that if not even provided on a physical carrier still must be accompanied by instructions for use and other labelling on paper they would probably say that you misunderstood the rule. Yet, this is precisely the sum of the medical devices and IVD directives and the e-Labeling regulation. The net result is that it is next to impossible to bring an app that is a medical device on to the market in a compliant way. The only way is to wedge the app in one of the exceptions for providing a paper IFU in the first place, for devices that can be used safely without any such instructions[5]. This thinking seems very outdated in a time in which most people deal digitally with all important information in their lives. In the meantime I have heard competent authorities say that this is not something they can reasonably require and therefore will not enforce against companies. But this is not formally on the record and of course absolutely not the way to solve problems that would have been easy to avoid. For example, the EU could have done something with a comitology amendment to the medical devices directive under article 11 (14), which would be a perfectly good legal basis to amend non-essential elements of the labelling requirement.

Apparently the EU institutions want the EU to be the dinosaur of healthcare.

You might expect this to have been fixed in the proposals for the medical devices and IVD regulation, if not by the Commission then surely by the Parliament because the Commission's own communication on the occasion of these proposals specifically refers to eHealth and the 2010 Digital Agenda for Europe[6] – well, no. They may have even read documents like the Commission's own policy and staff-working document 'eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century'.[7] Apparently mundane issues that concern entire developing markets that the EU really wants to stimulate have not been taken on board in a revision of medical devices legislation for decades to come.

Data protection

Next to medical devices regulation, predictable data protection regulation that poses a balanced regulatory burden on the mHealth industry is vital to the emergence and sustenance of a European mHealth market. Instead, we are faced with a proposed general data protection regulation proposal that stands to make processing of personal health data outside the scope of research under medical privilege so difficult and unpredictable, that even the biggest companies will have difficulties building business models that can be complaint. Here is the catch: the regulation has been set up as a general data protection regulation, a catch all instrument to protect the individual against the Googles and Facebooks of this world, who track and monitor your every move. However, what the EU never realised is that most of the things we do not like in social media, online sales and marketing, we really like and absolutely need in mobile health for the technology to work and be effective. Monitoring, profiling, tracking, data mining – these are all things that can lead to massive increases in health and wellbeing if implemented in the mHealth space[8]. Predictive intelligence is one of the big promises for population medicine to work and to keep healthcare spending under control[9]. Yet, the proposal makes any business model involving health data very difficult as has been made very clear by the combined associations of basically everybody active in eHealth and mHealth plus those active in healthcare in general in a position paper[10]. It seems however that this is falling on deaf ears.

Politicians compound this difficulty with the persisting controversy between Member States about the thing that would really help companies and should be core to the new instrument: the one-stop-shopping mechanism. This would make sure that only one Member State is allowed to regulate a data controller rather than all of them. In the meantime the regulation will impose strict privacy by design requirements that will severely affect user interface design, but the implementing instruments that will set out criteria are not even on the horizon yet.

Scope of new EU medical devices regulations

Then there is the newly proposed definition of medical device that came out of the Parliament's vote on the medical devices and IVD regulation[11]. This proposal adds 'indirect medical purpose' to the definition of medical device, causing an explosive expansion of the scope of medical devices regulations. It will create an enormous borderline minefield of software that has anything to do

with health one-way or the other. And it's completely outside the scope of the internationally negotiated GHTF definition of medical device.

As I write this I am at a conference in Brussels where both competent authorities and COCIR are saying this will not work. A competent authority says this would lead to a situation completely out of control because there is no way to meaningfully supervise the market that way.

To me as a lawyer it sounds like a very bad idea to tinker with the very foundations of medical devices regulation in a way that flies in the face of internationally agreed harmonised definitions just because the IVD regulation rapporteur wants to get a handle on predictive 'life style tests'[12].

One rational solution would have been that it be placed on an IVD regulation equivalent of the proposed Annex XV list in the medical devices regulation[13]. Instead, the Parliament is holding this definition over the market, while mHealth companies need to take decisions now for the next couple of years. They cannot rely on a possible Green Paper on the borderline of health that the Commission has delayed a couple of times now. As a result, they are now in regulatory limbo, because companies developing apps to manage food intake or lifestyle assistance need to plan for possibly being a medical device, even if this is never adopted in the end. But it may, so it's a known unknown that a responsible company must plan for, so an additional burden that may unnecessarily hamper innovation.

Conclusion

To quote one entrepreneur that moved away from the EU: "if dinosaurs were European, human beings would have never happened. You need to be able to say goodbye to the past and welcome something new. Europeans are not good at that."[14] This is not limited to the mHealth space alone. More in general, technology companies are suffering the consequences of 'regulatory rubble' as a result of the confusing messages the EU sends its entrepreneurs, regardless of the innovation friendly policy statements[15]. We have the REFIT programme[16], SMART regulation Council conclusions that say SMEs are very important[17], but we have little to show for it in practice, at least in eHealth and mHealth. I am still explaining to clients that they need paper push processes that nobody needs and that if DG CNECT wants something this does not mean DG SANCO supports it. Surely, when the e-Labeling regulation entered into force we already had mobile health and the legislator could have seen that this would not work in that market. I am explaining to clients that this new definition of medical device is so ill considered that it will probably not be adopted, but no guarantees. But in the meantime the damage is being done: Europe is putting the no in innovation by showing that it does not have a coherent, reliable and predictable regulatory approach to regulating the mHealth market.

Apparently the EU institutions want the EU to be the dinosaur of healthcare. We know however that healthcare in Europe is in a crisis and we know that we urgently need to take action to fix the system in a way that it actually improves medical devices in general[18]. We're allowing ourselves to waste a good crisis by not improving the no's to innovation. Presently the EU is definitely not the best place to be for mHealth, but it can be - if we only do something, and put our regulation where our mouth is.

Erik Vollebregt Founding Partner
Axon Lawyers
erik.vollebregt@axonlawyers.com
Follow Erik on Twitter @MedDevLegal

1. Lycocentre, § 45.
2. Lycocentre, § 46.
3. Proposal text for article 3 as amended by Parliament.
4. http://medicaldeviceslegal.com/2013/10/15/legal-recourse-against-delegated-and-implementing-acts-in-the-medical-devices-regulation/
5. Annex I 13.1 MDD.
6. Brussels, 26.9.2012 COM(2012) 540 final Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals, § 3.2.
7. COM(2012) 736 final and SWD(2012) 414 final.
8. See for example Eric Topol, 'The creative destruction of medicine: how the digital revolution will create better healthcare', Basic Books, 2012.
9. http://www.theguardian.com/healthcare-network/2014/jan/17/big-data-nhs-predict-illness?CMP=twt_gu
10. http://www.cocir.org/site/fileadmin/Position_Paper_2013/healthcare_coalition_on_data_protection_-__joint_statement__29_january_2013_final.pdf
11. http://medicaldeviceslegal.com/2014/01/13/imdrf-software-as-medical-device-definition-document-completes/
12. http://www.e-comlaw.com/ehealth-law-and-policy/news_preview.asp?id=1391
13. Annex XV as currently proposed contains a list for devices that do perhaps not have a medical intended purpose but will still be regulated as such because of their risk profile and similarities to medical devices.
14. http://www.euractiv.com/infosociety/tech-entrepreneur-eu-focus-innov-interview-532924
15. http://tech.eu/features/57/regulatory-rubble-europe/
16. http://ec.europa.eu/smart-regulation/refit/index_en.htm
17. http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/137331.pdf
18. 'Are We Wasting a Good Crisis? The Revision of the EU Medical Devices Directives and the Impact of Health Data Rules', Alex Denoon and Erik Vollebregt, European Journal of Risk Regulation 04|2013, p. 437.