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eHealth Hub to aid eHealth SMEs in navigating the legal maze

The European Commission, aware that SMEs in the eHealth space face considerable legal challenges in getting their eHealth ventures off the ground, has invested in assisting SMEs in this area. One such initiative is the new eHealth Hub, designed to provide legal guidance exclusively to eHealth SMEs. Here, Patrick Cahill, Solicitor and Manager at qLegal - Queen Mary University of London's legal service for startups and entrepreneurs - outlines the work of the eHealth Hub.

In April 2004, the European Commission published its eHealth Action Plan 'Innovative healthcare for the 21st century (2004-2011)' and this was followed in December 2012 with the second eHealth Action Plan of the same name ('2012-2020'). Both Plans detail the challenges and opportunities for eHealth in Europe. Not surprisingly some of the challenges include funding, an ageing population, an increase in the incidence of chronic diseases, market fragmentation and a lack of coordinated legal and regulatory frameworks.

The lack of a coordinated legal framework is important from the viewpoint of a number of stakeholders including patients, SMEs, innovators, governments, regulators, medical providers and investors. Part of the discussion in addressing legal issues in the 2012 Plan details that 'bringing down legal barriers is vital for deploying eHealth in Europe.' The Plan highlighted the application of patients' rights in cross border healthcare, the applicability of the EU legal framework on telemedicine services and the need for 'cross-sectoral legal work linking eHealth to other ICT-led innovation.'

The importance of ICT-led innovation is a key driver for eHealth growth. A 2008 report on telemedicine for the benefit of patients, healthcare systems and society discusses telemedicine as increasingly enhancing the access, quality, efficiency, safety and security of services and highlights the important role that European SMEs play due to their 'agility and innovation potential.' However the same report details that further support to extend the present 'window of opportunity' will be needed, for SMEs to continue innovating in the transition towards a less fragmented European marketplace.

As eHealth SMEs innovate and grow, the legal landscape in which they are operating in is rapidly changing and legal issues that are faced by them are becoming increasingly cross border. Not surprisingly, the European Commission has recognised that in order to support eHealth SMEs, there is a need for a move towards legal clarity in particular with regard to licencing, accreditation, registration, liability, data protection and reimbursement. Legal reform is balanced 'in such a manner that it benefits patient care while ensuring privacy and the highest standards of patient safety.'

The Commission has also invested in projects to assist eHealth SMEs in understanding and resolving their legal challenges. eHealth Hub is a new initiative exclusively focused on the digital health vertical and will provide long-term support to SMEs in this space.

Queen Mary University of London and the University of Amsterdam are both partners in the eHealth Hub and provide free (*pro bono*) legal support to eHealth SMEs in the UK and the Netherlands. Both legal services are provided by students under the supervision of volunteer lawyers.

Students are presented with the opportunity to engage with eHealth SMEs and provide written advice, a process which is of huge educational benefit to them, while SMEs receive advice for free (albeit often over a longer timeframe). The service also provides the universities with the opportunity to look at the legal needs of eHealth SMEs and the challenges that they are facing at a national and European level and to further influence policy in the area.

One client that attended qLegal (Queen Mary University of London's legal service for startups and entrepreneurs) was Bybreen Samuels. She is developing a prototype for a health tech product in order to help type 2 diabetes patients manage and reverse their illness. She sought the advice of qLegal in understanding the intellectual property rights applicable to her application, the data protection regime in the United Kingdom and Europe, and assistance in confidentiality and non-disclosure. Bybreen said: "In particular, I required

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advice on how the requirements of the Data Protection Act and the General Data Protection Regulation would apply to my business model as I would be collecting the sensitive personal health data of consumers." She continued, "the students from qLegal understood my business and provided really useful and practical advice which has helped clarify many legal questions that I had."

Bybreen is not alone in having difficulty navigating the legal aspects of growing an eHealth SME. At CLINIC (the University of Amsterdam's legal service for startups and entrepreneurs), students have recently selected two eHealth SMEs from the Rockstart Digital Health Accelerator to provide legal assistance to. Eyesense is an artificial intelligence company that provides software and hardware solutions to enable blind and visually impaired people to be more independent and to enrich their daily life experience. It recognises objects, familiar faces and some facial features like smiles and winks.

The students will also work with Sonovr, which uses virtual reality to revolutionise positive psychology. It will help people with their mental health, self-improvement and the ability to make positive behaviour changes. Veronic Sjistermans, Lawyer at CLINIC, said "Our involvement with eHealth Hub in

providing legal assistance to eHealth SMEs is a fantastic way for students to apply their theoretical legal knowledge to disruptive tech companies in the eHealth space. We look forward to working closely with Eyesense and Sonovr in understanding and resolving their legal questions." Students are also eager to learn and work closely with eHealth SMEs. One student reflected: "I very much appreciate the direct contact with clients and to put into practice what I was learning during my LLM was priceless."

However, legal clinics at universities like qLegal and CLINIC do have capacity constraints and therefore as part of eHealth Hub, a legal network of individuals specialised in advising eHealth SMEs in each EU jurisdiction will also be created. The network will provide eHealth SMEs with the opportunity to see the lawyers and law firms that are experienced in providing legal assistance to them and in what legal areas.

qLegal and CLINIC will also organise European legal workshops with specialists from the legal network. The workshops will be focussed on legal areas that have been highlighted by the Commission and clients of the law clinics as being important. In this author's view, workshops will provide a forum for European eHealth SMEs to come together, to discuss their legal

challenges and to learn from specialists and each other, in understanding the next steps they should be taking.

eHealth Hub's work is not only limited to legal support, and the development of business modelling assistance, investment help and the commercial acceleration of eHealth SMEs will provide the capacity for SMEs to innovate, grow and develop. It is this fostering of innovation in Europe that will set the market basis to generate business growth for eHealth. However, underpinning this requires a sound, coordinated legal framework and with the complexity of the legal issues eHealth SMEs face and their interrelationship with aspects of Community law, support such as sharing of good practices in order to improve legal and administrative frameworks in different jurisdictions will continue to be required.