The Summary Report on the EC Green Paper on mHealth

The European Commission ('EC') published a Summary Report on its Green Paper consultation on mobile health ('mHealth') on 12 January, which provides an overview of the responses from stakeholders to issues related to the uptake of mHealth in Europe. Alexander Csaki, Adriano Ros, Emma Drake and Clarissa Junge-Gierse of Bird & Bird assess the responses in brief and further consider the questions of interoperability, data protection and reimbursement in the context of mHealth adoption in Europe.

The global mHealth market is projected to reach nearly $21.5 billion by 2018 with Europe's share of the market growing faster than any other region[1]. To help secure this growth, the EC launched a public consultation on mHealth as part of its Digital Agenda in April 2014. In a Green Paper released with the consultation, stakeholders were encouraged to share their views on questions concerning the uptake of mHealth in the EU.

Overview

The consultation received 211 responses. Many respondents' focus lay on questions of data protection and interoperability. However, many of the respondents also expressed concerns about the complexity of the existing EU legal framework and raised questions regarding the safety and liability of mHealth solutions. Another important obstacle identified to the successful implementation of mHealth applications was the difficulty of market access for web entrepreneurs. Besides expressing concerns and legal risks, some respondents emphasised the benefits of mHealth, particularly the possibility of greater cost-effectiveness. Notably, a reference was made to a study that demonstrated efficiency gains of 50-60% for patients with Chronic Obstructive Pulmonary Disease[2].

The state of mHealth

So, what do the consultation's responses reveal about the respondents' view of the state of mHealth? To help answer that question, it is worth taking a step back to look at how the EC defines 'mobile health.' Firstly, it is classified as a sub-segment of the broader eHealth market and secondly, it is defined as any medical or public health practice supported by mobile devices, including mobile communication devices used for health and wellbeing services and mobile apps. In practice, this covers a wide range of applications from standalone smartphone apps to tablet devices integrated into a complex, bespoke hospital IT system. With such a broad remit, it is not surprising to see the divergence of responses received to the technology-related questions raised in the Green Paper.

The EC's summary of the responses highlights the key technical challenge as interoperability and connectivity of mHealth solutions with other IT systems and electronic health records. A read through the responses reveals that there are other technology issues at play, such as digital literacy of users, which also need addressing. The question now is whether the EC decides that these issues constitute barriers to the growth of the market and whether it should be seeking to remove them as part of the eHealth Action Plan for 2012-2020. Most respondents support the contents of that Action Plan as well as the need for an eHealth interoperability framework, which has already been put forward by the Commission.

The general 21st century trend of increasing mobile connectivity, data speeds and processing power means that more efficient systems for collecting and processing health information are possible. When you combine these general increases in speed and power and affordability with the proliferation of sensors and wearable devices, it is easy to see the potential of the mHealth market to revolutionise the provision of healthcare. However, to realise this potential, and to encourage adoption, there needs to be a higher degree of standardisation of personal health information across Europe. Such standardisation, along with the use of open standards and protocols for the collection and exchange of health data, would allow economies of scale to encourage outside investment into the mHealth industry.

As an example, the UK has seen a shift in focus by Government in the last 12/18 months, moving away from procuring large, single-source IT systems to focussing on smaller systems built to a specification that requires the use of standardised datasets and open communication protocols. This has been reinforced by the creation of the Standardisation Committee for Care Information, which is tasked with identifying, commissioning and implementing national information standards for the NHS. These are the sorts of national initiatives that could be championed by the EC and encouraged across the Member States to ensure a coherent EU approach is achieved.

Data protection

mHealth applications are touched simultaneously by various EU legal frameworks, and a particular focus of the consultation was the interaction between mHealth

applications and data protection laws. EU data protection is currently governed by an EU Directive, and the national implementation of rules on health data in various Member States has some level of divergence. Whilst the EC's summary of the consultation was keen to highlight areas of commonality, it is relevant to note that on closer inspection these national differences were apparent in the varying approaches taken by national bodies and companies in their responses, for example in the French recommendation to include certification of health data storage in the cloud, which is in line with existing requirements in France.

The questions on data protection focussed on data security, which is an area that has received considerable attention from both national authorities and the Article 29 Working Party. Although some 97 of the 128 respondents said they were in favour of 'strong privacy and security principles' according to the report, the majority of the solutions proposed by respondents are included in existing guidance on compliance with the current laws issued by such bodies. As was noted by eight respondents, the Article 29 Working Party has issued an Opinion[3] that provides specific recommendations for app developers.

Whilst these contributions are interesting, the discussion on data protection for mHealth apps is likely to be overtaken by events. The EC's draft General Data Protection Regulation continues to be negotiated, and the trilogue between the European Council of Ministers, Parliament and Commission is expected to commence by mid-2015. The foundations for any specific schemes for mHealth data must begin with an analysis of the position under the new Regulation.

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For a realistic prospect of obtaining a solution to many of the existing problems raised - such as the need for 'a middle way' between anonymisation and retaining enough personal data to allow effective research, or clarifying what information in an mHealth app is subject to additional protections as 'health data' - mHealth stakeholders must engage now with the existing legal reform process to protect their interests.

Role of public healthcare and public procurement

As pointed out by one of the respondents, policies to strengthen mHealth should aim to bring buyers and sellers together[4]. Furthermore, in the consultation, questions of reimbursement have been identified as one of the main obstacles for the implementation of mHealth[5], together with insufficient market access for web entrepreneurs[6]. Obviously, questions of reimbursement are a generic task of national health services and insurers, public sickness funds and other actors in the public healthcare sector. As already suggested in the Green Paper, a possible solution can be found by including mHealth applications in the nomenclature of reimbursable healthcare activities. As pointed out by one of the respondent's, apparently this has already taken place in Italy and the UK, concerning a mobile app for monitoring blood glucose[7].

Additionally, it has to be pointed out that the problem of restricted market access for web entrepreneurs can be tackled with a precise application of procurement law. Application of procurement law also offers additional benefits: as addressed in several of the responses, defining standards to guarantee interoperability is a major issue with the implementation of mHealth in the EU Member States[8]. As suggested by some respondents[9], procurement proceedings also offer opportunities here. However the special nature of mHealth applications may cause difficulties when drafting procurement proceedings. Especially, defining the procurement needs of public sickness funds and other public authorities in the healthcare sector can impose a challenge.

In this context, pre-commercial procurement and public procurement of innovative solutions can be a well-suited vehicle to resolve these issues. These special procedures can open up the potential to drive innovation for the development and implementation of mHealth applications in the EU.

Conclusion

All stakeholders will want to ensure that they are involved in ongoing discussions and the EC will need to take more considered time for reflection. We now await those discussions.

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2. http://ec.europa.eu/digital-agenda/en/news/mhealth-europe-preparing-ground-consultation-results-published-today
3. Article 29 Working Party Opinion 02/2013 on apps on smart devices of 27 Feb 2013.
4. Contribution by PHILIPS, General Comments.
5. Contribution by COCIR, p. 12 et seq.
6. Contribution by Sitra Studies, p. 32.
7. See contribution by COCIR, p. 12 et seq.
8. See for example contribution by PHILIPS, general comments.
9. See contribution by Roche, COCIR and Sistra studies.