AmCham EU's response to the public consultation on the Green Paper on Mobile Health

Mobile health: opportunities for future health systems

CONSULTATION RESPONSE

Executive summary

The American Chamber of Commerce to the EU (AmCham EU) welcomes the opportunity to participate in the European Commission's consultation on its Green Paper on Mobile Health. Developing and promoting innovative health solutions is one of AmCham EU's priorities. In its 2014 report *Forever Healthy: The 2020 Healthcare Consumer*, AmCham EU recommended that 'developing technology, including eHealth and mHealth, needs to be prioritised' to support a new healthcare paradigm that is capable of responding to the upcoming challenges.[1] As also stated in AmCham EU's position on 'Investment in Healthcare', basic eHealth services, available through a single point of access (e.g. a smartphone or tablet), such as scheduling office visits, accessing medical records, viewing test results, repeating prescriptions, checking payment status and collecting information on treatment options 'are highly valued by increasing numbers of citizens'.[2]

As the Green Paper states, the past few years have seen growing interest in the use of wireless technologies in healthcare – particularly remote monitoring technologies outside of traditional healthcare settings – which represents one of the main elements of new public policies that aim to respond to the challenges of an increasingly older population, provide better treatment with fewer resources and create large efficiencies along the 'continuum of care'. At the same time, the mass penetration of mobile consumer devices such as smartphones and tablets, with a related evolution of services towards app-based delivery, has been a catalyst for new forms of eHealth that have great potential to engage citizens, deliver more personalised care and create new, innovative business models that leverage the ubiquitous reach of mobile networks.

While these developments have created some dilemmas for public authorities, healthcare professionals and companies that provide mHealth services and products, they largely replicate old issues such as data protection, security, interoperability and reimbursement. In addition, besides regulatory and organisational aspects, education

[1]AmCham EU (2014), *Forever Healthy: The 2020 Healthcare Consumer*, available at http://www.amchameu.eu/Portals/0/2014/ebooks/Forever-Healthy/hcc2020/index.html

[2]AmCham EU (2012), *Explaining AmCham EU's Position on Investment in Healthcare*, available at http://www.amchameu.eu/DesktopModules/Bring2mind/DMX/Download.aspx?TabId=165&Command=Core_Download&EntryId=7340&PortalId=0&TabId=165

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to stakeholders, including end users such as citizens and patients, and improving health literacy are key to making mHealth a success. Much of the acceptance and effective use of mHealth applications depend not only on the understanding of the tools but also on knowledge about health. Citizens and patients have a considerable share in the success of mHealth applications, e.g. in promoting healthy lifestyles, prevention and better adherence – all factors that increase the efficiency of health systems.[3] In the following comments we provide our views on how the EU should tackle these and other aspects if it wants to support the adoption of innovative solutions across its Member States to the benefit of Europe's citizens and for the sustainability of healthcare systems.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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[3] AmCham EU (2014), *Forever Healthy*

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Data protection including security of health data

Which specific security safeguards in mHealth solutions could help prevent unnecessary and unauthorised processing of health data in a mHealth context?

Although concerns are often raised about the processing of health data in an mHealth context, it is important to remember that the current EU data protection framework does provide a comprehensive and coherent set of rules that protect citizens' personal data, across all economic sectors and technology platforms including mobile, with specific provisions for special categories of data such as health data.[4] This results in stringent Member State legislation about the processing of health data that forbids any unwanted sharing with third parties, with derogations allowed only for important reasons of public interest. The data protection provisions are complemented by the ePrivacy Directive, which prescribes that consent and clear and comprehensive information to the user are necessary in order to place data on, and retrieve it from devices.[5] The draft General Data Protection Regulation will create more harmonised conditions –including on consent requirements, data breach notifications and the level of security appropriate to the risks and the nature of the personal data at hand – even though national laws will still differ due to Member States' competences in the management of healthcare services.[6] Finally, the upcoming Directive on Network and Information Security, once approved, will further harmonise requirements for all operators of critical infrastructure, such as healthcare, to adopt appropriate steps to manage security risks and report serious incidents to the national competent authorities.[7]

Given that these detailed rules fully apply in the mHealth context, AmCham EU believes there is no need for technology-specific security requirements that would apply to the processing of health data involving mobile platforms. On the contrary, the regulatory framework should promote technology neutrality, interoperability and innovation and should continue to apply horizontally across platforms.

How could app developers best implement the principles of 'data minimisation' and of 'data protection by design' and 'data protection by default' in mHealth apps?

The three principles of 'data minimisation' and of 'data protection by design' and 'by default' are intrinsic to the existing EU data protection framework, which requires that appropriate technical and organisational measures be implemented to protect personal data and that personal data be processed only in ways that are adequate, relevant and not excessive for their purposes. The Article 29 Data Protection Working Party already identified in its Opinion 02/2013 on apps in smart devices some fundamental organisational and technical practices that app developers should comply with to ensure the protection of personal data at all stages of the design and implementation of an app. These relate not only to the principles of 'purpose limitation' and 'data minimisation' but also to the various security implications of processing. They include appropriate information and user controls, user

[4]Directive 95/46/EC
[5]Directive 2002/58/EC, as revised by Directive 2009/136/EC
[6]COM(2012) 11, Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)
[7]COM(2013) 48, Proposal for a Directive of the European Parliament and of the Council concerning measures to ensure a high common level of network and information security across the Union

identification and authentication, the decision as to where the data will be stored (e.g. device or cloud), minimising the lines and complexity of code, checks to avoid data from being unintentionally accessed, transferred or compromised, virtuous user practices and many more.

We believe it is essential for mHealth app developers and users to adhere to these good practices, which play a particularly important role given the sensitivity of health data. At the same time, we believe no specific technology or operational mandates should be introduced and that the guiding principles of 'data minimisation' and of 'data protection by design' and 'by default' are best upheld by leaving room for a variety of implementations based on an mHealth app's functionality (e.g. wellness or medical) and the different levels of risk involved. Similarly, the internal processes in place in the healthcare settings (e.g. hospitals and private clinics) and other entities involved in healthcare provision will also have an impact on how the administrative, physical and technical aspects of these principles are enacted in practice.

Big data

What measures are needed to fully realise the potential of mHealth generated 'Big Data' in the EU while complying with legal and ethical requirements?

The deployment and meaningful use of Electronic Health Records remains too low in the EU; without them, healthcare systems lack a major foundation to generate 'Big Data' by pooling single patients' health data in standardised formats – including data collected through remote patient monitoring technologies, most of which rely on mobile connectivity – in order to support not only more personalised care but also comparative effectiveness research into treatments and drugs. The current EU data protection framework establishes solid safeguards for the protection of citizens' health data, even though implementation varies by Member State; at the same time, it is the single most significant obstacle to capturing value from 'Big Data' because it limits the possibility of data sharing across organisations and borders (in some cases, through local data server requirements) and strictly limits processing to the specific purposes for which the data was initially collected. While these measures aim to protect citizens' privacy, they make secondary use of data for healthcare and research complicated if not impossible. Regrettably, the proposed General Data Protection Regulation – all the more the amendments adopted in the European Parliament's first reading – will create even more obstacles to the use of data-driven technologies that, when incorporated into healthcare delivery systems, can enable healthcare professionals to make better decisions, avoid patient errors, become more efficient and understand individual and population health more effectively.

AmCham EU believes that the potential of 'Big Data' can only be realised if the regulatory framework allows for the use of de-identified, aggregate and properly secured health data that can deliver innovations that will benefit patients and society. In order for the framework to be most effective, the Commission should continue to promote the adoption of internationally recognised standards for interoperable electronic health records (EHRs) across Member States and to strengthen educational efforts amongst key decision makers. Moreover, we encourage the Commission to work closely with Member States to ensure that Member State laws governing the processing of health data are harmonised to the fullest extent possible in order to generate the expected economies of scale and benefits for citizens and healthcare systems.

State of play on the applicable EU legal framework

Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?

AmCham EU believes that the existing EU regulatory framework for the safety and performance of medical devices has supplied a sound and solid foundation against which technological innovations can be assessed.[8] The 2007 revision of the framework explicitly brought software –including apps – into the regulatory scope and sufficiently clear definitions and guidance[9] exist to determine whether an app was intended to be used specifically for diagnostic and/or therapeutic purposes, i.e. whether it meets the definition of a medical device. The new Regulation[10] and the ensuing guidance should build on the many merits of the existing regulatory approach, which enables both a high level of safety and a cost-efficient market access for innovative products to the benefit of patients and healthcare professionals.

It must be considered that companies that are new to the medical device industry have to (at great expense in terms of finances and human resources) institute significant procedural, technical, policy, staffing and facility controls prior to marketing a medical device. The impact of regulatory compliance will have a considerable effect particularly on mHealth app developers, the majority of whom are individuals and small companies. The legal framework should therefore be progressive and help speed innovation while ensuring public safety.

In this respect, we are deeply concerned by the European Parliament's amendments to bring products with unspecified 'indirect' medical purposes into the scope of the Regulation, which will unjustifiably qualify as medical devices a number of non-invasive, non-medical products such as lifestyle and wellbeing apps, not to mention general-purpose consumer electronics such as smartphones and tablets. More generally, the vagueness of the term 'indirect' runs the risk of triggering many new disputes about how to regulate borderline products. Many such disputes have taken place in the context of today's Directive and the new Regulation should aim to correct, rather than exacerbate, this situation.

Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts?

Yes. However, AmCham EU believes the Commission's proposal for a new Medical Devices Regulation already takes the necessary steps to strengthen the regulatory regime and ensure it is enforced more consistently throughout the Member States.

[8]Directive 93/42/EEC, as revised by Directive 2007/47/EC
[9]MEDDEV 2.1/6, Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices
[10]COM(2012) 542, Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Patient safety and transparency of information

What good practice exists to better inform end-users about the quality and safety of mHealth solutions e.g. certification schemes?

AmCham EU welcomes initiatives such as voluntary mHealth app libraries and directories that can help citizens and healthcare professionals alike navigate the numerous, disparate apps available on the market. Moreover, some organisations are developing app marketplaces to allow a subset of the mHealth apps to be organised and made available to citizens and healthcare professionals, thereby removing some of the uncertainty and friction associated with the huge number of apps available.[11] We believe that any certification mechanisms or quality labels should be industry-driven and remain voluntary and affordable.

What policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

As a preliminary point, AmCham EU wishes to note that the policy objective of the EU regulatory framework applicable to mHealth is not to verify the 'efficacy' or effectiveness of products placed on the internal market, but to set out some general safety and performance requirements. We note that out of the 97,000 mHealth apps identified in the Green Paper only a fraction have a genuine medical purpose, while the vast majority are apps that provide lifestyle and wellbeing advice. Thus, most mHealth apps available on the market today do not meet the definition of a medical device and should consequently not be subject to Union action to set high standards of quality and safety. By contrast, the report mentioned in the Green Paper regarding mHealth solutions not functioning as expected refers to apps that claim to treat or cure medical problems, i.e. apps that meet the definition of a medical device. AmCham EU believes this latter kind of apps fall within the scope of the EU regulatory framework for medical devices and should be subject to the general safety and performance requirements based on their level of risk.

How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?

AmCham EU believes that the distinction should be kept in mind between those mHealth solutions that meet the definition of a medical device and those that don't. It is our view that only the former have functionality that can pose potentially relevant health risks to citizens in the event of a malfunction. To ensure the safe use of mHealth solutions having a medical purpose, in addition to the general safety and performance requirements set out in the EU regulatory framework for medical devices, we believe an ongoing dialogue between patients, healthcare professionals and manufacturers/developers is necessary to ensure that these solutions are used safely and can effectively improve healthcare delivery. Patients and healthcare professionals should be aware of possible risks as described by the manufacturer/developer and should report malfunctions to the manufacturer/developer in order to improve the device/app, reduce health risks and avoid misuse.

[11] HIMSS (2013), 'Mobile health apps: a practical guide for healthcare stakeholders', *mHIMSS Roadmap*

The role of mHealth in healthcare systems and equal access

Do you have evidence on the uptake of mHealth solutions within the EU's healthcare systems?

As correctly stated in the Green Paper, mHealth uptake still remains limited in Europe. Although technology exists today that can enable service providers and manufacturers to deploy reliable and interoperable connected devices through smart wireless communication technologies and cloud infrastructure, there is still a lack of simple business models supporting the massive adoption of mHealth services and applications. Solutions deployed so far have been tailored and developed for specific regional or local authorities, each having different requirements, for specific use cases and situations and for the remote monitoring of specific patient pathologies and treatments. This has led to the current state of numerous pilots but no mass-market adoption of mHealth due to the lack of interoperability and economies of scale.

What good practice exists in the organisation of healthcare to maximise the use of mHealth for higher quality care e.g. clinical guidelines for the use of mHealth?

Like eHealth, mHealth describes a broad set of technologies that can support a variety of health-related services along the continuum of care, from mobile access to EHRs to telehealth and telecare. For this reason, good mHealth practices will tend to be good practices in each respective service that utilises wireless technologies. For instance, the TeleSCoPE project has developed a code of practice providing a quality benchmark for healthcare professionals and patients using telehealth services.[12] Other good practices relate to the adoption of strategies to guide the effective use of mHealth apps, such as the 'innovation centres' or 'ecosystem models' that are being implemented in the US. Similar to app marketplaces, these models provide a sandbox in which third-party applications can be tested and vetted to ensure they work effectively in care workflows. Moreover, both the US government and the commercial sector are increasingly making data available to app developers through application programming interfaces (APIs) in order to develop applications for healthcare professionals and citizens.[13]

Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?

Much has been said about the lack of large-scale evidence from randomised control trials on the positive impact of services such as telehealth – which largely rely on mobile technologies – on cutting healthcare costs. The much-reported cost-effectiveness study in the context of the UK Whole Systems Demonstrator found that the cost of adding telehealth was on average 15% higher than delivering usual care.[14] More recently, a similar cost-minimisation analysis carried out by the Renewing Health project found that the average added cost of telehealth was 20% vis-à-vis the control group.[15] We believe these findings have suffered from fundamental flaws in the design of the trials, mostly due to the short time frame and to an ensuing lack of organisational change – i.e. the telehealth interventions

[12] http://www.telehealthcode.eu/
[13] HIMSS (2013), 'Mobile health apps'
[14] Steventonet al. (2013), 'Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial', BMJ346:f1035
[15] Kidholm et al. (2014), *REgioNs of Europe WorkINg together for HEALTH Final Report*, Version 1.3

were not implemented into daily operation, with traditional care services unaffected during the projects. This has effectively resulted in the simple addition of new staff and equipment costs for the telehealth interventions on top of regular healthcare expenditure.

By contrast, consistent evidence tells us that eHealth/mHealth solutions have an overwhelmingly positive quality impact on healthcare delivery processes in that they result in fewer emergency admissions, hospitalisations and bed days per intervention as well as reduced mortality, sometimes dramatically and beyond expectations.[16] However, due to 'siloed budgeting', the full value of these net gains is not always evident to single actors in the healthcare chain as they only tend to manifest themselves over time and thanks to scale economies, while the cost of new technologies is felt immediately by each actor making investment decisions in the short term. Moreover, benefits are distributed unevenly between healthcare providers, who bear most of the investment risk to build and maintain eHealth/mHealth systems, and citizens, who reap most of the benefits with little or no investment.[17]

While we encourage public authorities to continue to study the impact of eHealth/mHealth on reducing healthcare expenditure, we believe that any economic assessment should ensure that all benefits and costs are taken into account, rather than focusing on simple cost avoidance as has traditionally been the case.

What policy action could be appropriate at EU and national level to support equal access and accessibility to healthcare via mHealth?

We welcome the Commission's efforts to stimulate the adoption of innovative eHealth/mHealth technologies and services in the Member States. We believe that the new Horizon 2020 programme goes in the right direction in trying to learn from past experience and design projects that can go beyond the current patchwork of piece-meal pilots that have failed to create interoperable and scalable products. We encourage the Commission to be even bolder to make sure European funds, including cohesion policy funds, can be used to deliver interoperable mHealth services and applications that can create large-scale access to innovative technologies for Europe's healthcare systems and citizens.

AmCham EU also supports the Commission's objective, in its Connected Continent proposal, to leverage electronic communications networks and services to restore competitiveness, drive innovation and create smart, sustainable and inclusive growth.[18] Mobile networks will play an increasingly important role in achieving these objectives as consumers shift to mobile computing platforms such as smartphones and tablets and the Internet of Things becomes a reality, creating an explosion in mobile data demand. This is particularly relevant for sectors with special societal value such as healthcare, which will not only need additional capacity – e.g. to collect a growing array of vital signs – but must also rely on high-quality, robust, resilient and secure connectivity to deliver value-added services while protecting citizens' health data. We therefore think that a more innovative, harmonised and coordinated approach to radio spectrum authorisation in the EU is needed in line with ongoing RSPG, CEPT and ETSI activities.

[16]JRC-IPTS (2012), *Strategic Intelligence Monitor on Personal Health Systems phase 2 (SIMPHS 2): evidence consolidation – report on best practices and key drivers of success*
[17]Saluse et al. (2010), 'Assessing the economic impact/net benefits of the Estonian electronic health record system', *DIGIMPACT Final Report*
[18]COM(2013) 627, Proposal for a Regulation of the European Parliament and of the Council laying down measures concerning the European single market for electronic communications and to achieve a Connected Continent, and amending Directives2002/20/EC, 2002/21/EC and 2002/22/EC and Regulations (EC) No 1211/2009 and (EU) No 531/2012

Interoperability

What do you think should be done in addition to the proposed actions of the eHealth Action Plan 2012-2020 in order to increase interoperability of mHealth solutions?

AmCham EU believes that the actions contained in the eHealth Action Plan to foster the adoption of EU-wide standards remain valid, and indeed are even more critical, to increase the adoption of interoperable mHealth products and services where information can be pushed and pulled seamlessly and securely between systems thanks to end-to-end, plug-and-play connectivity.

We note that today established standards are already available and that specifications and profiles provided by organisations such as IHE and Continua can significantly expedite the testing, certification and implementation of innovative applications both inside and outside the hospital. However, these standards and profiles have been inconsistently adopted in the Member States – including in public procurement, which we believe should be one essential impact factor. We encourage the Commission to further raise awareness, and stimulate the adoption, of readily available, global standards and guidelines.

Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes, by whom and how?

Yes. AmCham EU believes that the interoperability of EHRs with information collected via mHealth services – particularly on high-priority health conditions through the appropriate use of remote monitoring technologies – will be essential to improve the quality, safety and efficiency of care while seeking to improve citizens' inclusion and engagement. We believe that this 'holistic' approach to interoperability will enable healthcare systems to more easily share EHRs across providers and citizens while benefiting from the interconnected value of health IT using apps and wearable technology. In particular, we believe that the release of open or semi-open APIs will allow developers to collaborate with healthcare systems on apps that, while protecting citizens' health information, have huge potential to deliver more personalised care by harnessing device-generated data in conjunction with EHRs.

Reimbursement models

Which mHealth services are reimbursed in the EU Member State(s) you operate in and to what extent?

Results from the Renewing Health project – assessing the design and implementation of different types of telemedicine services, which form an important part of mHealth – showed that in most cases the reimbursement system was the main obstacle to further rollout beyond the pilot phase.[19] The reimbursement landscape for telemedicine is different in each country, yet it is almost always characterised by a lack of long-term reimbursement mechanisms, which in turn compounds the lack of viable business models. For instance, in France there is no specific budget earmarked for telemedicine, and only some services such as telecardiology are partially reimbursed. Funds are distributed to

[19]Kidholm et al. (2014), *REgioNs of Europe WorkINg together for HEALTH Final Report*, Version 1.3

Regional Health Agencies from the national level for regional pilots, with the definition of sustainable financing models left to the regions themselves. Similarly, in Spain there is no specific budget devoted to telemedicine, while funds are allotted on a case-by-case basis to project implementations, thus limiting sustainability in the long term. In Germany, telemedicine is only financed through publicly funded research projects or individual contracts, over a limited number of years, between insurers and providers at Länder level outside the national health insurance system.

There are, however, some signs of innovation in the app space. One case in point is Dario, a blood glucose monitor so far available in the UK, Italy and New Zealand that plugs directly into smartphones, where data can then be uploaded to an accompanying app, with plans to launch a professional medical portal so that users can synch up that data with medical professionals.[20] The app itself is free, but the disposable test strips and glucose device are paid-for. In the UK, the NHS will give Dario a reimbursement code so that people can receive the device and strips from their pharmacy or online. Depending on the region and type of diabetes the person has, it's either fully or partially reimbursed. Dario also received national and regional insurance reimbursement approval in Italy.

What good practice do you know of that supports the refund of mHealth services e.g. payer-reimbursement model, fee-for-a service model, other?

It will be important that any framework allows for various business models, e.g. outcomes-based reimbursement (which, among various other services, also includes mHealth apps), a fee-for-service model and others. AmCham EU believes that cross-industry research – for instance, into banking and insurance transactions – can provide insight into how healthcare payers and providers will use mHealth applications to create both revenue opportunities and cost savings. What is unique about mHealth with respect to both the clinical and financial areas of healthcare is that it affords opportunities to provide new business models as well as methods of assessing costs in this sector. Healthcare systems, including both public and private players, will therefore be positioned to increase mobile transactions, transition many of those transactions from traditionally higher-cost channels and include and engage more citizens. As the healthcare industry makes additional mobile transactions possible, the potential returns on investment for healthcare systems will increase as consumers shift to the faster, more convenient and less expensive mobile channel to make payments and access care in personalised ways.

Liability

What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?

A distinction should again be made between those mHealth solutions that meet the definition of a medical device and those that don't. For the former, compliance with the requirements set out in the EU regulatory framework for the safety and performance of medical devices will be essential to mitigate liability risks for manufacturers. For the latter, the Directives on Consumer Rights,[21] Electronic Commerce[22] and Unfair Commercial Practices[23] apply.

[20] http://mydario.com/
[21] Directive 2011/83/EU
[22] Directive 2000/31/EC

As for healthcare professionals, a research project has studied the incorporation into clinical care of mHealth-generated patient data and documented professional liability concerns and the steps taken to manage them.[24] Most concerns involved healthcare professionals' fear that they couldn't keep up with the vast amounts of patient-generated data and could therefore potentially be unable to appropriately respond to important clinical issues that may arise from such data. The project highlighted the following strategies for healthcare professionals:

- Work with patients – including through appropriate informed consent forms – to achieve a common understanding of the types of data they would be sharing and how the sharing would take place;
- Monitor incoming data and triage as necessary, under appropriate safeguards, by allowing specifically trained non-physician staff to view the information first in order to able to communicate more frequently with patients and allow doctors to review the information only when it was clinically necessary;
- Establish medical emergency protocols, using traditional emergency communications channels when necessary, and implementing it when data indicates the possibility of a medical emergency; and
- Use appropriate judgment in deciding when patient-generated health data will be included in the professional health record to accurately document the services provided to the patient.

Research and innovation in mHealth

What specific topics would you provide for EU level research, innovation and deployment priorities for mHealth?

AmCham EU believes that research and innovation has a key role to play in rethinking healthcare services and how they should be delivered in a user-centric approach, before considering technology. As seen in previous comments, we believe that most of the barriers to the large-scale deployment of mHealth solutions stem from organisational rather than technical issues, ranging from an inconsistent adoption of already available standards, technology and infrastructure to a lack of integration between mHealth services into daily operation. We therefore encourage the Commission to fund innovation and deployment projects that can address the organisational implementation of interoperable mHealth services and applications on a large scale and consolidate the creation of new, connected 'care pathways'.

How do you think satellite applications based on EU navigation systems (EGNOS& Galileo) can help the deployment of innovative mHealth solutions?

AmCham EU believes accurate, real-time location technologies will play an important role in creating new and more user-centric healthcare services, improving efficiency and safety and streamlining care delivery both in and outside the hospital. To give one very simple example in the app domain, an asthma inhaler with a sensor that uploads information to a smartphone app with every dispensed puff could provide alerts to air-quality issues in the area, based on the user's current location. These

[23]Directive 2005/29/EC
[24]McGrawet al. (2013), 'Going digital with patients: managing potential liability risks of patient-generated electronic health information', *Journal of Participatory* Medicine5:e41

innovative services can already rely on multiple data sources such as GPS, cell tower location, Wi-Fi and Bluetooth Smart to deliver increased accuracy, including indoors. We believe EGNOS and Galileo will provide a useful additional layer, in this context, once they are both fully operational.

International cooperation

Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?

AmCham EU believes the Transatlantic eHealth/health IT Cooperation Roadmap can give Europe a useful incentive to advance on the path to achieving the necessary level of interoperability not just for basic patient summaries across the Atlantic but also as a basis for full-blown interoperable EHRs across the EU, so as to enable citizens' full secure access to their medical information and associated services on mobile devices.

In the area of software and apps, it will be important that the work of the International Medical Device Regulators Forum (IMDRF) on software as a medical device (SaMD) is taken into account, so as to ensure a good level of regulatory convergence while preserving the different legal frameworks governing medical devices in different parts of the world.

Which good practice in other major markets e.g. USA and Asia could be implemented in the EU to boost mHealth deployment?

AmCham EU believes that incentives for healthcare providers to implement interoperable EHR systems, particularly when these incentives are linked to services available to the population on mobile platforms and apps, can be an important tool to stimulate mHealth uptake and the inclusion of mobile technology into reimbursement mechanisms. The meaningful use requirements under the Medicare and Medicaid EHR Incentive Programmes in the US in order to receive financial incentives for the 'meaningful use' of certified EHR technology could act as a model in this respect.[25]

Access of web entrepreneurs to the mHealth market

Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they face? How can these be tackled and by whom?

To help get their products to the public, start-ups in the mHealth space have to navigate a tangled web of challenges, including not just funding but also regulations (e.g. compliance with the medical devices and data protection frameworks) and complex technical issues such as interoperability, particularly for those entrepreneurs who develop more advanced applications that need to work within established healthcare settings, where the enforcement of existing interoperability standards is often inconsistent. This is arguably the most serious obstacle for small mHealth entrepreneurs to enter the

[25] http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

healthcare market and grow their businesses. The EU-wide adoption of already available global standards and specifications will be key in creating better market entry conditions in this respect.

If needed, how could the European Commission stimulate industry and entrepreneurs' involvement in mHealth e.g. through initiatives such as 'Startup Europe' or the European Innovation Partnership on Active and Healthy Ageing?

AmCham EU believes that the use of EU funds – in their various forms including Horizon 2020 and funding opportunities under Startup Europe –are an important tool to address some of the weaknesses that hinder the entry of innovative mHealth entrepreneurs into the European healthcare market, particularly in terms of fragmentation and duplication. Further to this, it is also important to note that venture capital investment in mHealth technology has increased dramatically in the last few years. Mercom Capital Group, a consulting firm, estimates that of the €1.6 billion venture capitalists put into healthcare start-ups last year, €412 million went to mHealth businesses.[26] Corporate venture capital will therefore also play a role, and it is essential that European policies create the confidence for the venture-funding market to invest in innovative but often high-risk mHealth applications and generate the necessary return on investment.

[26]Mercom Capital Group (2013), *2013 Annual and Q4 Healthcare IT Funding and M&A Report*