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GREEN PAPER
on mobile Health ("mHealth")

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1. INTRODUCTION

Mobile health (hereafter “mHealth”) covers “*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*”¹.

It also includes applications (hereafter "apps") such as lifestyle and wellbeing apps² that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly.

mHealth is an emerging and rapidly developing field which has the potential to play a part in the transformation of healthcare and increase its quality and efficiency.

mHealth solutions cover various technological solutions, that among others measure vital signs such as heart rate, blood glucose level, blood pressure, body temperature and brain activities. Prominent examples of apps are communication, information and motivation tools, such as medication reminders or tools offering fitness and dietary recommendations.

The expanding spread of smartphones as well as 3G and 4G networks has boosted the use of mobile apps offering healthcare services. The availability of satellite navigation technologies in mobile devices provides the possibility to improve the safety and autonomy of patients.

Through sensors and mobile apps, mHealth allows the collection of considerable medical, physiological, lifestyle, daily activity and environmental data. This could serve as a basis for evidence-driven care practice and research activities, while facilitating patients' access to their health information anywhere and at any time.

mHealth could also support the delivery of high-quality healthcare, and enable more accurate diagnosis and treatment. It can support healthcare professionals in treating patients more efficiently as mobile apps can encourage adherence to a healthy lifestyle, resulting in more personalised medication and treatment.

It can contribute to the empowerment of patients as they could manage their health more actively, living more independent lives in their own home environment thanks to self-assessment or remote monitoring solutions and monitoring of environmental factors such as changes in air quality that might influence medical conditions.

In this respect, mHealth is not intended to replace healthcare professionals who remain central to providing healthcare but rather is considered to be a supportive tool for the management and provision of healthcare.

¹ World Health Organisation “*mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3*”, page 6

² Lifestyle and wellbeing apps primarily include apps intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals.

mHealth has the potential to play a key role in transforming our lives for the better . Yet it is imperative to ensure that technology is safe and secure for use by citizens.

The objective of this Green Paper announced in the eHealth Action Plan 2012-2020³, is to launch a broad stakeholder consultation on existing barriers and issues related to mHealth deployment and help identify the right way forward to unlock mHealth potential.

The Green Paper considers the potential of mHealth and its technological aspects and presents the issues where stakeholder input is sought. It also analyses mHealth potential to maintain and improve patients' health and well-being and encourage their empowerment.

Many of the issues may not be within the competence of EU law, but the EU can still act as a clearing house for best practice and can help to stimulate innovation in an area of huge potential.

On the basis of the responses to the Green Paper, the Commission may take steps at EU level to support mHealth deployment.

The Commission services are also publishing, along this Green Paper, a Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps.

2. POTENTIAL OF MHEALTH

2.1. Potential for healthcare

The healthcare systems in Europe are facing new challenges such as the ageing of the population, and increased budgetary pressure. In this context, mHealth could be one of the tools to tackle these challenges by contributing to a more patient-focused healthcare, and supporting the shift towards prevention while at the same time improving the efficiency of the system.

2.1.1. Increased prevention/quality of life approach

mHealth solutions can help detect the development of chronic conditions at an early stage through self-assessment tools and remote diagnosis while sharing data with care providers would facilitate timely intervention.

In this context, mHealth can help overcome patients' reluctance to seek help because of stigma or shame, as it is the case with mental illnesses, where only about every second person experiencing a disorder receives treatment.

Attention to prevention has the potential to improve people's quality of life and even extend life expectancy and could be accelerated by finding novel ways of promoting "healthy behaviours". In this respect, motivation and user engagement remain key and a fruitful area of research for behavioural economics.

³ European Commission eHealth Action Plan 2012-2020 Innovative healthcare for the 21st century, 07.12.2012

Finally, a more engaged population that is healthier longer is expected to contribute to reducing the financial pressure on healthcare systems in the EU.

2.1.2. More efficient and sustainable healthcare

mHealth could contribute to a more efficient way of delivering care through better planning, reducing unnecessary consultations and better prepared professionals receiving guidance on treatment and medication.

Estimates show that the use of tablet computers and other mobile devices could help healthcare professionals and paramedic staff save up to 30% of their time spent on accessing and analysing information⁴. The healthcare workforce could be used more efficiently, supported by real-time communication with patients, e.g. via the exchange of app users data.

mHealth could help healthcare systems deal with shrinking healthcare resources. More medical and care interventions could be done remotely or by the patients themselves, guided by monitoring and reporting systems, reducing hospitalisation. For example, it can provide for an efficient method of managing chronic diseases through remote monitoring and guidance, even allowing patients to stay at home, thus both improving patients' comfort and significantly cutting healthcare costs.

Finally, analysis of the big data that mHealth generates may help improve healthcare effectiveness and disease prevention by providing healthcare authorities with a more accurate and holistic picture of patients' illnesses and behaviours.

2.1.3. More empowered patients

mHealth solutions support the changing role of patients from a rather passive, to a more participative role while enhancing their responsibility over their own health through sensors that detect and report vital signs, and mobile apps that encourage them to adhere to diet and medication.

It can also raise citizens' awareness of health issues through easy-to-understand information about their health condition and how to live with it, thus helping them take more informed decisions on their health.

Many mHealth solutions use tools to improve self-motivation or increase treatment compliance, for instance by motivating users to achieve specific fitness goals or reminding them to take their medicine.

The shift towards patient-centric care may require the re-design of existing infrastructures and healthcare organisations, currently organised around healthcare professionals. Healthcare systems will have to open-up to the possibility of receiving data from patients (e.g. collected by mobile apps) and ensuring ubiquitous access to care, for example through online health platforms accessible by patients and doctors. This implies a change in the role of professionals who may have to remotely monitor patients and more often interact with them via e-mails.

⁴ PWC "Socio-economic impact of mHealth", page 17.

2.2. Market potential

2.2.1. mHealth market

In recent years mHealth has emerged as a complementary way of delivering healthcare building on the ubiquitous connectivity of mobile networks and the proliferation of smartphones and tablets.

The growth in wireless subscriptions, which has reached over 6 billion wireless subscribers in the world, has favoured the uptake of the mobile health and wellbeing market⁵.

The convergence between wireless communication technologies and healthcare devices on the one hand and health and social care on the other hand, is creating new businesses, while the redesign of healthcare delivery and the emergence of a 'silver economy' are highly promising markets.

A recent WHO survey⁶ shows that mHealth in the high-income countries is driven by the imperative to cut healthcare costs, while in developing countries it is mainly boosted by the need for access to primary care. The survey also showed that one of the more recent healthcare drivers in the EU is that of systems, which promote personalised care through wearable, portable, or implantable systems and give patients a more active role (called personal health systems).

In Africa and in Asia the majority of existing mHealth services focus on improving the efficiency of the healthcare workforce and systems. Another category of services especially significant in India, South Africa and Kenya includes prevention and awareness messages to limit the spread of infectious diseases.

As for mHealth revenues, a joint analysis by GSMA and PwC projects that the global mHealth market will reach the equivalent of US\$ 23 billion in 2017, with Europe accounting for US\$ 6.9 and Asia-Pacific for US\$ 6.8 billion, ahead of the North American market of US\$ 6.5 billion⁷. According to that report, remote monitoring treatment solutions constitute almost 60% of the total mHealth deployments in Europe. Solutions that increase the efficiency of healthcare workforce and systems make up nearly 15% of overall deployments, alongside health and wellbeing apps.

Earlier studies such as the Frost and Sullivan analysis of 2008 did not anticipate such a growth: the European mobile and wireless healthcare technologies market was only worth over €1 million at the time.⁸ The rapid uptake of mHealth in Europe can be partially explained by the unexpected advent of mobile apps.

Another study conducted by PwC and GSMA⁹ indicates that in 2017 mHealth could potentially save a total of €9 billion in healthcare costs in the EU. The largest savings would

⁵ ITU "Measuring the Information Society" 2012.

⁶ World Health Organisation "mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3".

⁷ GSMA and PwC, *Touching lives through mobile health* - Assessment of the global market opportunity February 2012.

⁸ Frost & Sullivan (2008) "Mobile/Wireless Healthcare Technologies in Europe "

⁹ GSMA, Socio-economic impact of, mHealth, June 2013.

be in the areas of wellness/prevention (€69 billion) and treatment/monitoring (€32 billion) considering the costs of the workforce needed to support mHealth (€6.2 billion).

2.2.2. *mHealth app market*

The market for mobile apps has developed very rapidly in recent years to become a key driver of mHealth deployment facilitated by smartphone penetration. Interestingly, this market is dominated by individuals or small companies, with 30% of mobile app developer companies are individuals and 34.3% are small companies (defined as having 2-9 employees)¹⁰.

In 2013, the top 20 free sports, fitness and health apps already accounted for a total number of 231 million installations worldwide, as per a recent IHS report.¹¹

According to Juniper *"a burgeoning market for healthcare peripherals and increasing smartphone processing power will result in the number of patients monitored by mobile networks to rise to 3 million by 2016."*

It is also foreseen that by 2017 3.4 billion people worldwide will own a smartphone and half of them will be using mHealth apps¹².

According to recent estimations¹³ 97,000 mHealth apps are currently available across multiple platforms on the global market. Approximately 70% of mHealth apps target the consumer wellness and fitness segments. 30% of apps target health professionals, easing access to patient data, patient consultation and monitoring, diagnostic imaging, pharmaceuticals information etc¹⁴.

3. ISSUES AT STAKE

This section seeks stakeholders' views on various issues which should be looked at as regards the development of mHealth. As healthcare systems' organisation is a national or regional competence, it focuses on cross-border European-wide issues and on possible coordinated action at EU level that could contribute to the scale-up of mHealth in Europe, in strict line with the subsidiarity principle.

3.1. Data protection, including security of health data

The rapid development of the mHealth sector raises concerns about the appropriate processing of the data collected through apps or solutions by individuals, app developers, health professionals, advertising companies, public authorities etc.

mHealth solutions and devices can collect large quantities of information (e.g. data stored by the user on the device and data from different sensors, including location) and process them,

¹⁰ IDC "Worldwide and U.S. Mobile Applications, Storefronts, Developer, and In-App Advertising 2011-2015 Forecast: Emergence of Postdownload Business Models".

¹¹ IHS report "The World Market for Sports & Fitness Monitors—2013 Edition".

¹² Research2Guidance (2013), "The mobile health global market report 2013-2017: the commercialisation of mHealth apps" (Vol. 3).

¹³ Idem as previous.

¹⁴ Deloitte study "mHealth in an mWorld", 2012.

also in third countries outside the European Economic Area, potentially in order to provide new and innovative services to the end user¹⁵.

A study revealed that only 23% of consumers have used any sort of mHealth solution. 67% said they would like to do “nothing at all” on their mobile phone in support of their health and 77% had never used their phone for health-related activities¹⁶.

Consumers might be concerned about the risks posed to their health information, such as unwanted sharing with third parties (e.g. employers or insurers). Indeed, 45% of consumers say they are concerned about the unwanted use of their data when using mobile devices for health-related activities¹⁷.

According to a *Financial Times* investigation, 9 of the top 20 health-related apps have been found to transmit data to one of the dominant companies tracking details about people’s mobile phone use¹⁸.

This information will be in many instances personal data since it is information relating to a natural person who is directly or indirectly identified or identifiable. In addition, the processing of data concerning health is particularly sensitive and therefore requires special protection.

There are also legitimate concerns about the security of individuals' health data when using mobile health technologies as their personal data could be accidentally exposed or easily leaked to unauthorised parties.

This could be the case when healthcare professionals access health information from a mobile device or when patients store personal data on a personal health record application. Loss or theft of devices storing sensitive information can be a serious security issue.

Given the sensitive nature of health data, mHealth solutions should contain specific and suitable security safeguards such as the encryption of patient data and appropriate patient authentication mechanisms to mitigate security risks. Security and access control should also provide a fertile ground for future research and innovation projects.

Personal data protection is a fundamental right in Europe, enshrined in Article 8 of the Charter of Fundamental Rights of the European Union, as well as in Article 16(1) of the Treaty on the Functioning of the European Union (TFEU). Compliance with personal data protection rules, with information of the data subject, data security, and the lawful processing of personal data, including of health and medical data, is therefore vital for building trust in mHealth solutions¹⁹. Guidance exists on data protection requirements for 'apps'.²⁰

¹⁵ See also section 3.8 on "Big data".

¹⁶ Boehm, E, Mobile Healthcare’s Slow Adoption Curve, 2011, Forrester Research, Inc.

¹⁷ Blue Chip Patient Recruitment. Leveraging Mobile Health Technology for Patient Recruitment, October 2012

¹⁸ Financial Times, Health apps run into privacy snags, 1.09.2013

¹⁹ See accompanying Staff Working Document on the existing EU legal framework applicable to wellbeing apps, paragraph on Right to privacy and to data protection.

²⁰ See the Opinion 2/2013 of the Article 29 Working Party of 27 February 2013 on apps on smart devices.

In the EU, the currently applicable Personal Data Protection Directive²¹ is being revised in order to better respond to challenges posed by the rapid development of new technologies and globalisation while ensuring that individuals retain effective control over their personal data: the Commission's proposal for a General Data Protection Regulation²² will provide for further harmonisation of data protection rules in the EU, ensuring legal certainty for businesses and increasing trust on eHealth services with a consistent and high level of protection of individuals.

The proposal also introduces inter alia the principles of "data minimisation", "data protection by design", and "data protection by default" to make sure that data protection safeguards are taken into account at the planning stage of procedures and systems.

Questions:

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

3.2. Big data

mHealth can facilitate the mining of large amounts of health data. Such data (e.g. of measurements, medical images, symptom descriptions) can be stored in large databases with the potential to boost healthcare research and innovation.

Big data is the capacity to analyse a variety of (unstructured) data sets from a wide range of sources. This requires the capability to link data and extract potentially valuable information from unstructured data in an automated cost-effective way.

Personal sensor data is expected to grow from 10% of all stored information to approximately 90% within the next decade²³. Real-time data collection is expected to contribute towards more individually targeted drug therapies.

These data can be a vital element of epidemiological research as they can enable researchers and scientists to improve patient treatment by looking for patterns on a larger scale or draw new conclusions, for instance on the relation between the development of a medical condition and environmental factors. Big data can also contribute to a reduction of trial periods for medication or to the development of more advanced mechanisms for early detection and prevention of diseases. It could also allow for the development of innovative business models in the field.

²¹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281/31, 23.11.1995.

²² Commission proposal for a regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data, COM(2012) 11.

²³ *Improving Public Health and Medicine by use of Reality Mining*, Pentland. A, et al 2009, Robert Wood Johnson Foundation.

Maximising the potential of health data could lead to increased productivity, and cuts of cost in the healthcare sector, with prospects of USD 300 billion in value in the US healthcare sector per year²⁴.

Data mining of health data must however be done in compliance with legal requirements, including for the protection of personal data and may give rise to ethical issues, in particular regarding the respect of the principle of informed and explicit consent, where that is relevant, e.g. if the patient did not expressly permit his personal data to be used for research purposes at the time he was asked for his consent.

The fundamental right to personal data protection fully applies in a big data context. As a consequence, the processing of personal data has to be done in compliance with data protection rules, in particular given the sensitive nature of health data; of particular relevance in that context are the definition of personal data and the purpose limitation principle.

Researchers face the challenge of efficiently using the vast amounts of health data collected from mobile devices while ensuring that these data are processed in a secure way. For that purpose, the eHealth Action Plan 2012-2020 announced that EU funding on research and innovation should also focus on the ways to analyse and mine big data to the benefit of citizens and researchers amongst others.

Cloud computing²⁵ also plays a significant role in increasing the data storage and processing capacity required to handle such an amount of data, ensuring its accessibility anytime and anywhere. The European Commission cloud computing strategy aims to facilitate faster adoption of secure cloud solutions in Europe, which should support secure storage of health data over the Internet²⁶.

Processing of individuals' health data should strictly comply with EU data protection rules, which are currently under revision²⁷.

Questions:

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

3.3. State of play on the applicable EU legal framework

The eHealth Action Plan 2012-2020 indicated that the rise of mHealth is blurring the distinction between the traditional provision of clinical care and self-administration of care and wellbeing; and that different actors were seeking clarity on their roles and responsibilities in the value chain of mobile health²⁸.

²⁴ McKinsey report, *Big data: The next frontier for innovation, competition, and productivity*, May 2011.

²⁵ Cloud computing refers to the storing, processing and use of data on remotely located computers accessed over the internet.

²⁶ COM(2012) 529, "*Unleashing the Potential of Cloud Computing in Europe*", 27.09.2012.

²⁷ See accompanying Staff Working Document "*on the existing EU legal framework applicable to lifestyle and wellbeing apps*", paragraph on right to privacy and to data protection.

²⁸ See eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century, page 9-10

Furthermore, the recently adopted resolution by the European Parliament on the eHealth Action Plan 2012-2020 underlines the potential of mobile health and wellbeing apps for patients and the need to have a clear legal framework to ensure their development and safe adoption²⁹.

As the use of these apps is affected by existing EU regulatory instruments, stakeholders, such as mobile app developers and mobile platform manufacturers, may seek guidance as to the applicable rules. A state of play as to the relevant EU rules is presented in the accompanying Staff Working Document.

In the EU, there are no binding rules as to the delimitation between lifestyle and wellbeing apps and a medical device or *in vitro* diagnostic medical device. Since January 2012, in order to help software developers and manufacturers identify whether their products fall or not under the Medical Devices Directive³⁰ or the *in vitro* diagnostic medical devices Directive³¹, the Commission's services have issued some guidance on this issue, which will be continuously updated. According to this guidance, depending on their intended purpose, apps may fall under the definitions of a medical device³² or of an *in vitro* diagnostic medical device and consequently will have to comply with the relevant provisions of the aforementioned directives.

Since this delimitation is not yet clarified through binding rules, when the Medical Devices Directives do not apply to apps, clarity is required as to the rules with which they must comply. The fact, that Union legislation could not yet address latest developments in this sector and that the Court has not had the opportunity to clarify the applicability of existing legislation on these newly developed apps, still leaves room for interpretation.

There may be a need to assess the legal issues arising from the use of lifestyle and wellbeing apps, in view of the potential safety risks they may pose to citizens' lives.

Questions:

- Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?
- Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if yes, why and how?

²⁹ Resolution of 14 January 2014, <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0010+0+DOC+XML+V0//EN>

³⁰ Directive 93/42/EEC on medical devices, OJ L169, 12.07.1993. This directive is currently under review to become a regulation.

³¹ Directive 98/79/EC on *in vitro* diagnostic medical devices, OJ L331, 7.02.1998. This directive is currently under review to become a regulation.

³² In the United States the Food and Drug Administration (FDA) published in September 2013 a Guidance on Mobile Medical Applications to inform app manufacturers and distributors about how it intends to apply its regulatory authority to apps intended for use on mobile platforms. The FDA approach calls for oversight of only those mobile apps that are medical devices and whose functionality could pose a risk to a patients' safety if the app does not function as intended.

3.4. Patient safety and transparency of information

Over 97,000 mHealth apps are currently available across multiple platforms on the global market³³. Despite interest in apps and enthusiasm for their use, they have yet to enter mainstream of healthcare provision, and in many respects are still viewed as a novelty.

Given their variety, consumers, patients or healthcare professionals may find it difficult to choose the right mHealth solution or app.

The safety of mHealth solutions and lifestyle and wellbeing apps may be cause for concern, explaining the potential lack of trust. Reports underline that some solutions do not function as expected, may not have been properly tested or in some cases may even endanger people's safety³⁴.

In addition, the information these solutions provide can sometimes be insufficient as to who developed them and whether they have undergone appropriate reviews or followed established medical guidelines or clinical tests.

Safety may be demonstrated by using user safety standards³⁵ or specific quality labels. Certification schemes could also be reliable indicators for healthcare professionals and citizens as they could verify whether the app or mHealth solution delivers credible content, contains safeguards for user data, and functions as intended.

App certification programmes are already emerging like the National Health Service online Health Apps library in the United Kingdom, where all apps have passed a review to prove their safety and compliance with data protection rules³⁶. Other examples exist where apps are certified and sold on specialised app stores, such as Happtique in the US.

Some initiatives focus more on the transparency of the information about reliable health apps like the first European Directory of Health Apps. It contains facts about 200 mHealth apps recommended by European patient groups and covers a wide range of health related topics, such as medication reminders, diseases, exercise and physical impairment.

Finally, safety concerns arise when citizens can use the results of an mHealth solution or app to take decisions on their own which can potentially endanger their health or when the mHealth solution erroneously states the person is healthy.

mHealth solutions are not meant to replace doctors. They may help people stay healthy and/or support patients in managing their health conditions. In some cases, it may be necessary that doctors accompany patients in their use of these solutions.

³³ Research2Guidance (2013), "*The mobile health global market report 2013-2017: the commercialisation of mHealth apps*" (Vol. 3).

³⁴ The New England Center for Investigative Reporting, Boston University, "*Lacking regulation, many medical apps questionable at best*", 18.11.2012.

³⁵ An example of a standard on user safety is the draft standard IEC 82304-1 of the International Electrotechnical Commission (IEC). It contains requirements for software that are medical devices, while intended to be used with a broader scope, such as for health and wellbeing purposes.

³⁶ Another example is the AppSaludable Distinctive created by the Andalusian Agency for Healthcare Quality, an app certification programme.

Questions:

- What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?
- Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?
- How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?

3.5. mHealth role in healthcare systems and equal access

The ageing population³⁷ and the rising number of chronic disease patients are increasing the burden on EU healthcare systems, resulting in rising hospitalisations, continuous care and steep healthcare costs.

mHealth is one of the tools that could help EU Member States maintain sustainable healthcare systems as it could support more efficient delivery of care. It should be noted that the work pressure of health care professionals is high. Introducing mHealth services may, in the beginning, require training in order to adapt and develop their digital skills.

It could keep chronic disease patients outside of hospitals and help tackle the shortage of healthcare professionals in Europe. It is estimated that approximately 15% of healthcare utilisation costs could be saved through remote monitoring, using mHealth solutions³⁸.

mHealth can contribute to a more equitable access to healthcare as technologies spread to remote areas and people that would otherwise not have easy access to healthcare. It could also help ease access to healthcare by people with disabilities. Such shifts in access are already noticeable in many developing countries thanks to mobile phones (in particular SMS)³⁹.

However, mHealth is currently not used to its full potential in the European healthcare systems. Healthcare providers and potential payers may need further evidence of its clinical and economic benefits before they scale up its adoption.

In this respect, the European Commission facilitates cooperation and the exchange of scientific information among EU Member States through a voluntary network of national experts on health technology assessment⁴⁰.

According to a Eurobarometer survey, only a third of Europeans have Internet access through their mobile phones, with significant differences between Member States: widespread

³⁷ See the 2012 Ageing Report: Economic and budgetary projections for the 27 EU Member States (2010-2060), chapters 3 and 4

³⁸ Mc Kinsey and GSMA, "*mHealth: A new vision for healthcare*", 2010.

³⁹ World Health Organization, mHealth - New horizons for health through mobile technologies 2011

⁴⁰ Article 15 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, L 88/45, 4.4.2011.

availability in Sweden (63%) whereas mobile Internet is still emerging in Bulgaria (13%) and Portugal (16%)⁴¹.

mHealth strongly depends on high capacity, ubiquitous and flexible networks. In this context, the Commission recently adopted a legislative package for a *"Connected Continent: Building a Telecoms Single Market"*⁴², which recognises the need of high-speed and high-quality networks, inter alia for eHealth, while aiming at a greater degree of harmonisation and more investment within the single market.

Finally, under Horizon 2020, the Commission will provide funding for mHealth and intends to support among others, digital health literacy of healthcare professionals and citizens⁴³ as it is key to ensuring that mHealth contributes to equal access to healthcare.

Questions:

- Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems?
- What good practices exist in the organisation of healthcare to maximise the use of mHealth for higher quality care (e.g. clinical guidelines for use of mHealth)?
- Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?
- What policy action could be appropriate at EU, as well as at national, level to support equal access and accessibility to healthcare via mHealth?

3.6. Interoperability

The absence of standards that mandate interoperability⁴⁴ between mHealth solutions and devices impedes innovation and economies of scale. This also prevents mHealth investments from being utilised well and limits the scalability of such solutions.

The slow uptake of international interoperability standards⁴⁵ is even more problematic for the app market as it is dominated by SMEs and individuals (i.e. app developers)⁴⁶. The latter may not necessarily have resources for legal advice or knowledge of multi-layered standardization activities. Consequently, they may favour short-term strategies for quick market access.

⁴¹ Special Eurobarometer 381 E-COMMUNICATIONS HOUSEHOLD SURVEY, June 2012.

⁴² <http://ec.europa.eu/digital-agenda/en/connected-continent-legislative-package>.

⁴³ The new EU funding programme for research and innovation for the period 2014-2020.

⁴⁴ SemanticHealth study definition "*Interoperability is where two or more eHealth applications (e.g. EHRs) can exchange, understand and act on citizen/patient and other health-related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors or organisations within and across health system jurisdictions, in a collaborative manner.*"

⁴⁵ However, some international and European standardization committees, such as IEC, CEN-CENELEC, ISO have an increased number of working groups related to health informatics.

⁴⁶ 30% of mobile app developer companies are individuals, while 34.3% are small companies (defined as 2-9 employees) according to IDC "*Worldwide and U.S. Mobile Applications, Storefronts, Developer, and In-App Advertising 2011-2015 Forecast: Emergence of Postdownload Business Models*".

Users can benefit from transferring data they have generated on their mobile devices to their personal health records or healthcare provider. Access to user-generated data could help health professionals when setting a diagnosis. They could also consider integrating this data into their patients' electronic health records ('EHR')⁴⁷.

These possibilities raise multi-layered interoperability issues (i.e. semantic, technical, organisational and legal) similar to the ones raised on eHealth in the eHealth Action Plan 2012-2020, where a series of actions were proposed.

Ensuring interoperability in eHealth is complex. For instance, millions of terminologies and vocabularies are required to describe and code health data⁴⁸. This complexity is compounded by the wide heterogeneity of health information systems in the Member States (implemented by health authorities, hospitals, or doctors etc.)⁴⁹.

The eHealth Network, established under Directive 2011/24/EU on Patient Rights, is leading the development on EU eHealth guidelines. It aims to enhance interoperability among electronic health systems and to ensure access to safe and high-quality healthcare.

The study on the European Interoperability Framework for eHealth⁵⁰ describes a vision and a process on how to assess, endorse and share a common set of interoperability standards, profiles and procedures relevant to the electronic provision of healthcare services, in order to ensure that eHealth (including mHealth) systems across the EU are able to communicate with each other.

A first step towards the setting-up of such common interoperability frameworks has been the adoption of the guidelines on minimum (non-exhaustive) patient summary dataset⁵¹ by the eHealth Network of Member States in November 2013 to be shared across borders.

Questions:

- What, if anything, 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?
- 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?

3.7. Reimbursement models

A major obstacle preventing mHealth solutions to reach the mainstream of healthcare provision could be related to the lack of innovative and adequate refund models.

⁴⁷ eHealth Task Force report recommendation.

⁴⁸ E.g. SNOMED CT is one of the most comprehensive, multilingual clinical terminology in the world and is composed of more than 300.000 concepts and about 1 million descriptions.

⁴⁹ The slow computerisation of healthcare systems is another issue that impedes the provision of integrated care.

⁵⁰ http://ec.europa.eu/isa/actions/documents/isa_2.12_ehealth1_workprogramme.pdf

⁵¹ http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf

One existing model is based on reimbursement by institutional payers and national authorities, which decide whether mHealth can be included into the nomenclature of reimbursable healthcare activities. Currently, some national legislations still provide that a medical act can only be performed with the physical presence of both the patient and his doctor, preventing the reimbursement of mHealth solutions.

National health services are beginning to implement innovative refund models, such as incentive programs.⁵² It may be in the payers' financial interest to actively support their affiliates in staying healthy. In this respect, insurers are proposing to their subscribers specific mHealth solutions that promote healthy behaviours in return for a reward, e.g. refund of a suggested health app or a free smartphone. The goal is to improve people's overall health through behavioural change.

Users' role in bearing the costs for these solutions needs careful assessment. As regards lifestyle and wellbeing apps, users often pay for their apps via app stores. Cases are emerging where a partner can pay for these apps (e.g. a pharmaceutical company) in the context of an existing therapy⁵³.

Creating incentives for healthcare professionals to use mHealth solutions also requires reflection, for instance by remunerating them for care activities outside of the classic consultation (e.g. request for information by e-mail).

Questions:

- Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?
- What good practice do you know of that supports refund of mHealth services (e.g. payer-reimbursement model, fee-for-a service model, other)? Please give evidence.

3.8. Liability

The issue of identifying potential liability arising from the use of an mHealth solution may be complex, because of the numerous actors involved: the manufacturer of the mHealth solution, a healthcare professional, any other care professional involved in the treatment or the electronic communications provider providing the internet.

The damage to patient health can come from various sources: a defective device; a wrong diagnosis by the healthcare professional based on inaccurate data; an error by an IT specialist; the patient did not use the device correctly or sent the wrong data to his doctor. This list is not exhaustive and cannot envisage all the possibilities of risks.

⁵² Article from McKinsey & Company "*Engaging consumers to manage health care demand*", January 2010.http://www.mckinsey.com/insights/health_systems_and_services/engaging_consumers_to_manage_health_care_demand

⁵³ "My VisonTrack has worked closely with a large pharmaceutical company in clinical trials. The partner may provide the app to the user for free and reimburse my VisonTrack directly.", *Comparison of US and EU Regulatory Approaches to Mobile Health Apps: Use Cases of Myvisiontrack and USEFIL*, European Journal of ePractice, n°21, page 40.

App developers, mHealth manufacturers and healthcare professionals may request greater legal clarity on the liability risks they may face for having developed or prescribed an app that harmed the user's health and on the ways to mitigate those risks.

Questions:

- 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?

3.9. Research and innovation in mHealth

Diet, exercise and other wellness apps are wildly popular with consumers, but it is questionable whether most of them do more than provide information⁵⁴.

There is a need to invest more in research and innovation in the field to support the development of more advanced and innovative mHealth solutions while ensuring a high degree of efficacy and reliability as well as secure processing.

EU funding schemes aim to create incentives for the development of innovative mHealth solutions. The funding of mHealth projects began under the *5th framework programme of the European Community for research, technological development and demonstration activities* (FP5), in 1998.

Over the years, the EU has funded various projects on Personal Health Systems and Patient guidance services, involving the use of smartphones and other mobile devices as well as space enabled applications. These projects have focused on proof of concept, small-scale medical validation and medical outcome expected to lead to new care paths triggered by mHealth. Recently, a series of mHealth projects focused on the development of mobile solutions to centralise individuals' health data and keep them up to date, while increasing patient empowerment.

mHealth funding will continue under Horizon 2020⁵⁵ prioritising mobile technologies and applications for integrated, sustainable, citizen-centred care. A key objective is to enable citizens to become co-managers of their health and wellbeing with the help of ICT.

The European Innovation Partnership on Active and Healthy Ageing (EIP AHA) can also support the development and deployment (large-scale roll-out) of more innovative mHealth solutions. It aims to improve the sustainability and efficiency of healthcare systems and boost the competitiveness of innovative ICT products and services in the field of active and healthy ageing.

Questions:

- Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?

⁵⁴ IMS Institute for Healthcare Informatics "*Patients apps for improved healthcare, from novelty to mainstream*", October 2013

⁵⁵ The new EU funding programme for research and innovation for the period 2014-2020.

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

3.10. International cooperation

According to a WHO report on mHealth, healthcare systems around the world *"are under increasing pressure to perform under multiple health challenges"* such as chronic staff shortages, and limited budgets, while solid evidence on the efficiency of mHealth is still lacking. Economic disparity is also reflected in the degree of mHealth uptake where higher-income countries show more mHealth activity than lower-income countries⁵⁶.

In this context, the WHO-ITU joint agreement on mHealth for non-communicable diseases (NCDs)⁵⁷ intends to scale-up already approved mobile technology in 8 priority countries at least one drawn from each geographical region⁵⁸. The European Commission is looking to contribute to the implementation of this agreement.

The EU-US Memorandum of Understanding (MoU) on eHealth/Health IT is a good example of cooperation as it seeks to facilitate more effective use of health-related ICT to support the health of the population, while strengthening the EU-US relationship and supporting global cooperation in that area.

In the field of medical devices, regulatory convergence is under way within the International Medical Device Regulators Forum (IMDRF)⁵⁹, set up in 2011 to replace the Global Harmonization Task Force. Its participating regions (US, EU, Canada, Japan, Australia, Brazil, China and Russia) recently endorsed key definitions for software that are medical devices.

Considering mHealth's cross-border dimension and its potential contribution to sustainable healthcare systems and the economy, stronger support is needed for more regulatory convergence in the field and the exchange of good practice internationally.

Questions:

- Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?
- Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?

⁵⁶ WHO report *"mHealth - New horizons for health through mobile technologies"*, 2011. - WHO Countries in the European Region are currently the most active and those in the African Region the least active

⁵⁷ NCDs are diseases that cannot be passed from one person to another such as cancer, heart disease or diabetes.

⁵⁸ Mobile solutions will be primarily sms or apps based and will include a range of services focused on awareness, training, behavioural change, treatment and disease management etc.

⁵⁹ The IMDRF is a voluntary group of medical device regulators from around the world, to discuss future directions in medical device regulatory harmonization and to accelerate international medical device regulatory harmonization and convergence.

3.11. Access of web entrepreneurs to the mHealth market

One of the conditions for the successful uptake of mHealth is the web entrepreneurs' capacity to enter this promising market, which is crucial to support the European ambition of becoming a front-runner in this field.

The Digital Agenda for Europe supports a series of entrepreneurship initiatives under "Startup Europe"⁶⁰ - a platform for tools and programmes supporting people who want to set up web start-ups in Europe. This could contribute to stimulating the market entry of European web entrepreneurs on the mHealth market.

In addition, the Commission launched a study called "Eurapp" to understand the impact of the app economy in Europe on growth and job creation. This understanding will ensure a better implementation of the web entrepreneur actions of the Digital Agenda and other initiatives.

The eHealth Action Plan 2012-2020 also puts forth actions that support web entrepreneurs: networking of European high-technology accelerators to give advice (e.g. legal, financial, technical) and training to eHealth start-ups. This should improve the market conditions for entrepreneurs developing products and services in the fields of eHealth and ICT for wellbeing.

Questions:

- 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?
- If needed, how could the 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?

4. NEXT STEPS

All interested parties are invited to submit their views in response to the above questions. Contributions should be sent to the following address to reach the Commission **by 3 July 2014 at the latest**:

CNECT-GREEN-PAPER-mHealth@ec.europa.eu.

European Commission

DG Communications Networks, Content and Technology

31, Avenue de Beaulieu

Unit H1, Health & Well-Being

⁶⁰ <https://ec.europa.eu/digital-agenda/node/67436>

Brussels 1049 - Belgium

The consultation can also be responded to on the website of the Digital Agenda for Europe, under the section "consultation".

As a follow-up to this Green Paper and on the basis of the responses received, the Commission will announce possible next steps in the course of 2015.

Contributions received will be published on our website unless a contributor requests otherwise. It is important to read the specific privacy statement accompanying this Green Paper for information on how your personal data and contribution will be dealt with.