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mHealth

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OVERVIEW

There are many new challenges related to the healthcare system. There is one important factor, which can be used as a game changer - new technologies. Especially, all kinds of the digital possibilities: new medical inventions and devices, networks for connectivity of data exchanging information and human cooperation, data processing centers, applications for physicians and patients, data storage for referential knowledge on trends and symptoms, devices and wearables for measuring state of health. All - accessible and interoperable all over the Europe.

This game changer is also coming from the new achievements in the research area related to health problems - as for example: European Innovative Medicines Initiative (IMI). There is a medical approach, which allows using molecular insights into health. The crucial role is played by genetic factors. The use of "-omics" technologies and biomarkers can give us more knowledge of the human body and genetic dependencies. It is important to have the possibility to translate the "-omics" to clinical applications used in new models of diagnosis and treatment, which can be really personalized.

Medical services can be personalized in all aspects: from much more friendly delivery of e-prescriptions to individual models of therapies. It will create the background for the reorganization of the whole healthcare system and make it much more oriented at the patients' needs. This is the way to build the preventive healthcare system: using early warning tools due to real time health state monitoring, giving individuals the possibility to take the self-responsibility for their own health.

We should challenge problems related to the digital literacy, which means: better access to the fast internet for all people, with adequate, sufficient skills enabling usage of all digital tools. It could be the key factor for creation new demand in the area of healthcare - for much more efficient and users-friendly.

Those new phenomena require stronger cooperation and synergy among activities made by the EU level institutions (all stakeholders) and national governments and partners. It needs new forms of biobanking and terms for data analytical possibilities: clear rules governing the process of data exploring and sharing them, processing and comparing the data, making them useful for clinical activities and ensuring the right to information to all subjects. All those efforts should be implemented under the conditions of the new GDPR (General Data Protection Regulation), but with consideration how to use Big Data opportunities for the new quality of the medical services in the broader sense.

Responding to this challenge will definitely pay off.

1/ Introduction – challenges

1. With 37% of the European population expected to be age 60 or over by 2050, in addition to the rise in chronic diseases and the current constraints on public finances, European healthcare systems are required to deliver more — and better — care with reduced resources. Traditional healthcare systems set up for acute care can no longer cope with these challenges without a fundamental transformation. This transformation does not have the potential to achieve sustainable healthcare without discovering new opportunities. Concrete innovative actions are needed to make the transformation of healthcare systems a reality, from acute care to chronic care, from hospital dependency to integrated care across all levels of health systems, as well as from cost and volume to value and outcome. Health expenditure is an average of 9% of the gross domestic product (GDP). In most member states, more than 70% of health expenditure comes from public sources.

> **It will be the paradigm shift from the traditional care model focused on treating and responding to diseases to the new one, based on avoiding diseases if it is possible by prevention and early warning systems.**

2. There is one important factor, which can be used as a game changer - new technologies. Especially, all kinds of the digital possibilities: new medical inventions and devices, networks for connectivity of data exchanging information and human cooperation, data processing centres, applications for physicians and patients, data storage for referential knowledge on trends and symptoms, devices and wearables for measuring everyday state of health.

This game changer is also coming from the new achievements in the research area related to health problems - as European Innovative Medicines Initiative (IMI). There is a medical approach, which allows using molecular insights into health and disease. The crucial role is played by genetic factors. The use of "-omics" technologies and biomarkers can give us more knowledge of the human body and some genetic dependencies. It is important to have the possibility to translate the "-omics" to clinical applications used in new models of diagnosis and treatment, which can be really personalized. All those new phenomena require stronger cooperation between research and healthcare system, new forms of biobanking and terms for data analytical possibilities: clear rules governing the process of data and sharing them, processing and comparing the data, making them useful for clinical activities and ensuring the right to information to all subjects.

This personalized medicine - in the broader meaning is very often referred to as a 4P: predictive, preventive, personalized, participatory (patients' empowerment). Now, there are some solutions in the area of telemedicine, e-health in the broad sense, and mHealth. mHealth is oriented at using all dimensions of the mobile opportunities: networks, devices, applications for improving healthcare at many levels. The uniqueness of mHealth is related to the personalized forms of its use.

These reflections have led to the identification of three main opportunities that should guide the transformation of healthcare systems.

2/ General opportunities – guidance for transformation of healthcare systems

Investing in prevention and early intervention

3. Prevention means intervening before something becomes a serious health issue, including eradicating, eliminating or minimising the impact of a disease and a disability or, if this is not feasible, slowing the progression of a disease and a disability. Early intervention, on the other hand, is the process of providing specialist interference and support services for a person who needs them, either early in the course of life or at the onset of the development of a health problem. Using mHealth solutions, based not only on technologies, but at the same time on the effects of the new research, could be enormously supportive for prevention models development.

It can be addressed to all possible groups: elderly people, who due to these solutions may live longer and in better health, for persons with disabilities, who need support in many areas of their functioning, for parents taking care of their children, for people with chronic diseases, whom can benefit from permanent monitoring of the state of health. Last but not least, mHealth contributes also to the wellbeing of all people and is related to the new lifestyle needs and demands.

Fostering empowered and responsible citizens

4. Fostering empowerment and awareness of the responsibility within citizens involves assisting individuals with discovering and developing the inherent capacity to be more responsible for one's own health. Healthcare systems will be more adaptive if individuals understand their rights, responsibilities, capabilities and opportunities to remain healthy and manage their own health in the most appropriate setting, providing that the political and economic context empowers them to do so. This is the new phenomenon: **health literacy, which is becoming the key factor for the healthcare shift paradigm.**

Information sharing, coupled with sustained investment in education, will also enable citizens to better understand their health condition and participate in the decision--making process in order to plan and manage their own health care plans, which will result in better outcomes. It is important to establish much more effective institutional framework for information sharing, also among healthcare institutions, authorities and all stakeholders. The adequate usage of various types of new technologies (social networks, platforms, websites, communication apps) can help to disseminate knowledge on the new mHealth opportunities and raise the awareness of the responsibility for health everyone has as an individual.

5. mHealth is widely recognized as a tool offering huge potential for supporting, educating and empowering citizens. Currently, the majority of applications are geared towards organizations or professionals rather than the public. Nevertheless, it is essential that healthcare professionals and doctors are involved in designing mHealth programs for citizens so that the information spread is accurate.

Reorganising care delivery

6. Successful reorganization of care delivery should adopt a transparent bottom-up approach to build trust and synergies between different stakeholders. It also includes Information and Communication Technology (ICT) applications to enable lean processes and new organisational methods. Thanks to new technologies, the new organisational model of healthcare systems can be much more oriented on the patients' needs and expectations. **Medical services can be personalised in all aspects: from much more friendly delivery of e-prescriptions to individual models of therapies.** This patient centric model is a background for the reorganization.

7. The reorganization of healthcare delivery models and systems cannot take place without the involvement of governments, providers, patients, insurers and health professionals. The complexity of healthcare systems in various regions and countries poses the challenge of achieving integrated care. It is obvious that there is no single, best approach. **It is not possible to develop a "one-size-fits-all" approach.** However, governments and policymakers can learn from the experiences of others. In addition, the promotion of the best practices in the systemic implementation of the mhealth solutions is strongly desired.

8. There is a continuous need of simultaneous activity at the EU and national level:

a) Now, after the adoption of the General Data Protection Regulation and at the beginning of the process of the implementation (two years period, probably to the mid of 2018) it is significant to enable appropriate use of data to ensure a well-informed health intervention strategy, while ensuring that patients' privacy is protected. The work on the application plan for the General Data Protection Regulation is specifically required, as it is necessary to create the right framework for delegated acts, focused on cross-border usage of health data, and for rules regulating the usage of masked health data for research analysis.

This is not the end of the process, it is the starting point. The role of the Big Data related to the healthcare area will be growing very rapidly. In the coming future - the improvement of the mHealth and the impact the mHealth has on the whole healthcare system will depend strongly on using analytical data possibilities. The problem of the ownership of data, models of data flow and sharing, terms for anonimization and pseudonimization, cross border collections of data, geolocalization of data storages - all those things will be important to the development based on trust. We will have to face many new problems, but in any case we need to establish future-proof solutions;

b) Member States need to encourage initiatives that foster the implementation of prevention and early intervention programs in the workplace. Furthermore, efforts should be made to identify and share best practices in prevention strategies on the local level;

c) Member States, with the support of the European Commission, need to fully transpose the Directive on the application of patients' rights in cross-border healthcare with the intent of improving citizens' access to information on healthcare systems and developing and implementing information and education programs for citizens on medical technologies and care available. We need to ensure the fast growth of the position and the level of usage of the EU-wide eHealth Network;

d). Member States' governments should develop programs aimed at increasing the level of health literacy among the general population. This would be key to an improvement in health outcomes and a reduction in healthcare costs. This is the general purpose, but nowadays it is obvious - that we need digital health literacy;

e) To all partners such as European institutions and Member States: it is important to address the dilemma - **what we need to do at the European and national level to support this paradigm shift in the direction of the mHealth influencing the whole healthcare area.** How can we build the background for the synergy? Creating the synergy is the only way to take common responsibility, to share the responsibility for our goals both at the European and national level. And it will be the only way to overcome challenges that appear when we think of the "integrated care". There are some programs implemented and efforts made, but this solution requires **the visible and commonly understood ROAD-MAP and powerful LEADERSHIP.**

9. When we consider the growing role of the mHealth solutions, we should face problems related to the digital literacy, which means ensuring better access to the fast Internet for all people with adequate, sufficient skills enabling usage of all digital tools. It could be the key factor in creation of the new demand in the area of healthcare, as well as much more efficient, users-friendly, and properly personalized medical services. We need this demand as a game changer for both sides of medical serviczes in general: doctors and patients. But this, so called, market demand will be stimulated under one key condition - the technology development. In order to achieve these technological inventions need to be fully implementable and need to have reasonable and profitable business models. But, there is a special, additional aspect connected to the growth in demand. This demand directed to the new model of healthcare area is not coming from medical professionals, from politicians and institutions. It is coming from technology companies and, most importantly, from patients, from consumers, from app users, from the new lifestyle. The fundamental background to this demand is based on the good response to new habits related to the digital revolution. Due to the new technologies we can develop an early warning system that would be time effective, relatively cheaper, oriented on the fast intervention, user friendly, helpful in everyday life, open to self-health management (self-responsibility), well-being oriented, giving us as patients and consumers the right to protect personal data, to protect the consumer's right to be informed on our data and our health condition. **This kind of demand, also based on lifestyle expectations is supportive for starting the structured and comprehensive changes.** This is an unbelievable great challenge we face while changing the model and the rules resulting in the paradigm shift.

10. One of the key aspects in the context of the paradigm shift in the healthcare systems is assessing the changes on the basis of 'diseases avoided' rather than 'diseases treated' criterion. **Five key lessons**:

A Health is wealth: supporting healthy citizens to have access to high--quality care must remain a top priority for Europe. We must never lose sight of our primary goal: ensuring the well-being of citizens and securing healthcare systems;

B There is no one-size-fits-all solution: rather than wait for the one magic formula or solution, policy makers should actively encourage and support innovative initiatives, reward excellence and achievement, and scale up successful projects;

C Both failures successes constitute valuable lessons: not every idea will work in every country. However every country can and should contribute its own ideas, pilot programs and innovations to the larger convergence. Exchanges between different countries on successes and lessons learnt will lead to broader positive impacts across European healthcare systems;

D The use of new technologies can change healthcare systems: new opportunities to shape medical services offered by new ways of processing various data sets (-due to sensors in personal devices measuring the state of health and due to deep genetic analysis and "-omic" technologies) translate into personalized services bringing new quality and effectiveness. The key aspect is - cooperation among the research area, technology inventions, and literacy of all stakeholders, legislators, business and patients, because this new healthcare model is patient centred;

E The only way to be successful is to create the synergy between all possible activities undertaken by the European institutions at the European level (various partners) and real efforts made by national governments in Member States. Now, we feel the lack of strong cooperation and leadership. If we want to make real and effective change in the healthcare area, we need to call all stakeholders for action.

Potential, benefits of Digital Health

11. EU healthcare systems face significant challenges that are creating concerns about the sustainability of healthcare delivery. The combination of increased prevalence of chronic disease and ageing population trends is exacerbating the healthcare costs and negatively affecting healthcare delivery.

12. The use of mobile and wireless technologies to support the achievement of mHealth has the potential to transform the face of health services delivery across the European Union. For example, "early indications of the Whole System Demonstrator Programme in the UK show that if used correctly, the use of technology as a remote intervention can lead to: a 20% reduction in emergency admissions, a 14% reduction in bed days and a 45% reduction in mortality rates. Trials in Nordic countries show that mHealth could generate a 50-60% reduction in hospital nights and re-hospitalization for patients with COPD. Taking data collected from pilots and projects in Scotland and Norway, it is estimated that mHealth could reduce overall elderly care expenditure by 25%."[1]

13. Many mobile health proposals have gained acceptance and are generally being more widely adopted. Over 800 mHealth deployments exist worldwide, more than 120 of which are in Europe. Examples of mHealth in Europe:

Wellness

Tips about immune system strengthening, measures to protect from and prevent seasonal diseases, unconventional therapy to treat seasonal diseases, and tips on dietary supplements and healthy eating habits.

Prevention

personalized smartphone applications designed to help people over the age of 12 to take greater control of their asthma. Some apps for asthma keep users posted on local information about asthma triggers. It also tracks symptoms and ACT scores over time to see trends that can be shared with their providers.

Monitoring

Smartview remote monitoring allows healthcare providers to access to valuable cardiac data and alert messages from Sorin's devices while the patient is at home. In addition, the device offers advanced diagnostic capabilities and early detection of cardiac disease progression.[2]

[1] The Boston Consulting Group and Telenor Group, The Socio-Economic Impact of Mobile Health, April 2012
  - All About That App' from March, (Plum Consulting) 2015. http://www.plumconsulting.co.uk/pdfs/Plum_March_2015_All_about_that_app.pdf
  - Emerging m-Health: path for growth (Price Waterhouse Cooper) – 2014 http://www.pwc.com/en_GX/gx/healthcare/mhealth/assets/pwc-emerging-mhealth-full.pdf
[2] - eHealth – Technology for health (EPRS) March 2015 http://www.europarl.europa.eu/RegData/etudes/BRIE/2015/551324/EPRS_BRI%282015%29551324_EN.pdf
  http://www.gsma.com/connectedliving/wp-content/uploads/2012/03/mHealth_Regulatory_medicaldevices_10_12.pdf

14. In 2017 in Europe probably 185 mln people could be regular mHealth users: 26 mln from ageing population, 61mln as patients with one or more lifestyle disorders, 54 mln at risk of developing lifestyle disorders, 22.6 mln as chronic patients that could benefit from enhanced wellness and prevention etc. (GSMA, Connected living). It can result in potential 99 bln USD healthcare cost savings.

It is important to understand some facts and figures, because they are showing the real processes in the area of healthcare. They are showing the increasing role of the market demand related to the expectations and possibilities of all players at the market. These factors are connected with:

Patients/Citizens – The number of people who use mobile health apps will double every two years. In 2013 there were only 16% of people using these applications. It is estimated that in 2015 this figure will reach 32%. Similarly, the number of people with a smartphone who will download health apps is believed to reach 50% by 2017. As of today, 49% of patients are willing to use wearables for health reasons.

Business – 84% of the total revenue in the mobile health market will come from related services and products, such as sensors. Only 9% of the total revenue will come, in the next five years, from downloading apps. It shows: that investments in innovation are the key condition!
Due to the increasing use of smartphones and the growing number of chronic illnesses, the mobile health global market will reach 10.2 billion dollars by 2018.

Clinical area – Not only patients use smartphones to improve their health. A significant number (15%) of mobile health apps are targeted to health professionals. These include CME (Continuing Medical Education), health care management and remote monitoring apps. In 2016, there will be growth in the number of clinical apps. It is important to start education among patients and physicians to acquire health literacy!

Data obtained via mobile technologies will become Big Data. Thousands of patients could provide evidence and real-life evaluation of therapeutic outcomes. **83% of the population is willing to provide their medical data if used for research and to improve their health condition.**

Technology - "Digital mHealth Platforms" will consolidate. This type of platforms will be able to track data from several sources (wearables, smartphones, glucometers, etc.) and link it, offering patients, as well as health professionals and careers, a general vision of their health in real time. This will change radically the connection between the ecosystems and will redefine how health is managed. It can create the new attitude - the self-responsibility for health.

mHealth will become the hub in which the development will be based on IoT. Through the empowerment of patients, the usage of molecular insights into health, the advances in genomics and behavioral health, the vertical system of health will become obsolete, and a new connected model will emerge at every level. **It will be the background for the personalization of the medicine in many dimensions.**

15. A powerful combination of factors is driving the change in the area of healthcare. These include rapid advances in mobile technologies and applications, a rise in new opportunities for the integration of mobile health into existing eHealth services, and the continued growth in coverage of mobile networks. mHealth is no different from other areas of eHealth in its need to adopt accepted standards and interoperable technologies, ideally using open architecture. The use of standardized information and communication technologies would enhance efficiency and reduce cost.

mHealth can constitute valuable additional tools to the provision of care and may support patients' empowerment and motivation, facilitate contacts between physicians and patients living in remote areas, improve the quality of the health services delivery, as well as their efficiency. It allows patients to be connected to services which include health information on demand, health record management, and the remote, real-time monitoring of chronic conditions such as diabetes, asthma, and hypertension.

16. The key value of using new technologies in the healthcare area is related to the new model of all medical services - **personalized services based on technological inventions and personal devices, as well as the results of research oriented on using molecular insights into health and disease.** Those kinds of services, now possible to implement, are focused on individual features of patients and, due to processing all types of data, can differentiate and fit the therapies. They can also contribute to building the early warning system for patients and shaping the new relationship between doctors and patients. In healthcare, the patient-doctor relationship is based on mutual trust. The human dimension is at the core of this relationship. Efficiency of treatment outcomes highly depends on these variables. While the use of new technologies, such as mHealth applications, inevitably introduces a distance factor in the patient-doctor relationship, it should not weaken this trust-based approach. On the contrary, mHealth requires higher level of trust between patients and healthcare professionals. It is important to underline that mHealth solutions, as well as eHealth services in general, are not seen as a substitute to face-to-face interactions between doctors and patients. They rather come as a complement.

All those potential chances and benefits can create not only the positive response to the demand expectations (individual needs initiated by the companies with the offer of simple apps, helpful in everyday life), but also build the systemic advantages - for the healthcare system as a part of the public health policy. This means not only a better quality of medical services in many areas. **Improving quality is going directly with saving money, which is the real cost effective opportunity.** The health systems across Europe are facing many new challenging issues such as ageing societies, increase in chronic diseases and deficits in funding. The paradigm shift of healthcare model can offer new prospects.

3/ Risks and barriers to mHealth implementation

17. mHealth is still in a relatively early stage of adoption and development. Many recent studies indicate that health information security, patient confidentiality, standardized metrics, and interoperable systems were identified as pertinent policy challenges to overcome before the consideration of mHealth as a strategic initiative.

Of course this is a multi-step process, which includes public awareness campaigns (highlighting the need and potential solution/benefit), research and development (innovation), trials and their evaluation to prove effectiveness, and guidelines for use (part of policy). The policy-making process rarely keeps up with technological development or public's demand; this is especially true in the context of mHealth – where technology evolves so quickly and where multiple sectors are involved (e.g. health, communications, and technology).

18. We need the new model of framework, both legal and non-legal, for real evolution in the area of broad eHealth development, including mHealth solutions. **It should not be over-regulated. It should rather be focused on establishing the flexible background for the legislation catching up with technological developments.** We need to ensure that new technological achievements in the healthcare area will meet all standards - via proper certifications approved by legitimate authorities, adequate procedures present in codes of conducts and some forms of co-regulation, not always in 'strong legislation': EU directives, regulations or national laws. It is necessary to do it based on the experience already gathered due to elaboration of the directive related to the adjustment of the new medical devices to the required standards with possibilities of taking certificates from proper institutions.

In general, we can make the framework for those new solutions, which will be based on: strict legislation on the European and Member States level, soft law in the form of guidance, or codes of conducts as a way to achieve the best practices dissemination, as well as certification schemes. This is the way to laborate rules and a framework for the solutions and make them much more future-proof and oriented on the consumers' purpose: satisfaction.

19. Data security and privacy are areas that require legal and policy attention to ensure that mHealth users' data are properly protected. Legal frameworks that govern the integrity of health data transfer and storage, in addition to identifying access control and medical liability are critical to enabling mHealth in the Member States. But at the same time the cooperation is much more needed. Respecting the rules set in the General Data Protection Regulation and cooperation in the development of best practices (e.g., data anonymization, encryption, user consent requirements) will ensure that data can move more safely and effectively between different mHealth systems and applications. Trust and confidence are key elements enabling the swift uptake of mHealth applications by end-users.

In general it is agreed that health professionals and patients perceive telehealth as being largely industry driven, rather than by addressing the actual needs of end-users[3]. Taking into account the expectations of patients and health professionals it is essential to ensure trust towards the final products and hence guarantee a high uptake. In the coming future we should also be able to ensure adequate safeguards by using only devices adjusted to the model of security and privacy by design, which will be crucial for the mobile world, including mHealth. The interoperability requirements and portability rules are needed for making the flow of data secure.

If we want to make TRUST a basic requirement for mHealth development, we have to ensure certain conditions such as physicians' credibility and clear principles for liability, transparent, understandable, ethical rules for data processing and transferring, security at the high level - of systems, as well as infrastructural security related to the devices via security and privacy by design, full respect for patients as consumers and their rights.

20. Quality and reliability of mHealth applications are also crucial elements to take into account. Without these elements ensured, it is very improbable that patients and doctors would trust those apps, which may have a backlash effect on their global uptake. The boundary between mHealth applications that fall under the scope of the EU medical devices legal framework[4] and applications that are rather considered to have a wellbeing or recreational purpose is blurred.

This deivision should be clarified in order to ensure that mHealth applications that have a medical purpose are properly regulated under the applicable EU legal framework. **These processes would need to be in line with the medical devices legislative framework and provide for effective European harmonisation rather than being left at the initiative of the Member States.** In addition to safety and reliability guarantees, physicians willing to use mHealth applications, would expect that the medical service they provide is legally viable. Similarly to general eHealth services, it is presumed that physicians might be reluctant to use such applications, if liability provisions are not clarified from the start. The remuneration of services provided by physicians outside the usual consultation framework, i.e. with support of mHealth tools, would also need to be addressed. This is particularly true in a cross-border situation.

21. Two types of quality safeguards are also needed for mHealth applications serving the purpose of promoting well-being. The first one should be focused on the protection of individual's data, and the second one has a great meaning for the merit side of the quality of services. In the case of the second safeguard, the approval and quality certification processes could be envisaged, whereby mHealth applications would undergo a strict scientific review process based on generally accepted evaluation processes. This aspect still needs consideration. It is a matter of patients' safety in general, not related to the serious decisions made during the assessment of the health condition or therapy, but important for the sake of patient's self-assessment of his or her condition.

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[3] Chain of Trust final report, FP7 Project, 2013: http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf
[4] It is duly acknowledged that some mobile applications are to be considered as medical devices under Directive 93/42/EEC, as in vitro diagnostic medical devices under Directive 98/79/EC or as Radio Equipment and Telecommunications Terminal Equipment (RTTE) under Directive 1999/5/EC

From overcoming barriers to adoption

22. Multiple regulatory, economic and structural barriers are limiting the adoption of mHealth. The need for harmonisation between health and mobile regulatory frameworks, the lack of incentives to healthcare providers towards mHealth solutions and the absence of clearly defined business models limit the speed of adoption of mHealth solutions. There are only few technological limits for future development and adjusting technological inventions to the medical needs. **Better conditions assuring mHealth development need to be imposed at a proper pace adjusted to the people's demand for mHealth solutions. This will enable the usage of mHealth technology as broad as possible.**

23. But there are some active barriers:

a) Clarity needs to be provided on how medical device regulations apply to mHealth, providing a clear pathway for certification. In particular, manufacturers and applications developers need the clearer understanding of the difference between regulated medical devices/applications - and recreational/well-being ones. **We need clarification of a borderline between medical apps and lifestyle/wellbeing apps** (we should also consider the impact of the wearable devices development, which will incorporate health and fitness apps). It is one of the key problems for the future development in the mHealth area. As it was expressed earlier, we will different solutions in different areas. Sometimes we will have to implement legislative solutions, but in some - other spheres soft law, or quality labelling/certifications;

b) The absence of regulations or standards that mandate interoperability among mHealth solutions and devices limits the scope of innovation and economies of scale to be achieved. It has also a negative impact on ease of use and limits scalability. **The lack of the proper interoperability at the European level is one of the key barriers** - all kinds of interoperability: cross border, semantic, legal, organizational, technical. The impact of standards is particularly important as standards may provide for a technical means to tackle the lack of harmonisation at other levels, e.g. legal and institutional, across Member States;

c) The relations between various mHealth solutions, models and telemedicine schemes should be more transparent. The new environment related to the Internet of Things needs to be created to enable the functioning of those forms of mHealth. There are many possible cooperation modes, interactions and data exchange possibilities. Measuring some symptoms by mobile devices should be linked to the telemedicine devices, as teleradiology for instance, and used in order to ensure a better diagnosis. It requires transparent and clear rules and standards;

d) **A deep analysis related to the assessment of possible cost reduction in the healthcare systems is also needed.** New technologies, especially new mHealth solutions, will change the healthcare systems in a complex way and will create the e-healthcare in the broad sense, which will contribute to substantial savings. The lack of the analysis in this respect and the lack of constant monitoring of costs within the healthcare system, both using the mHealth solutions and not, is blocking the mHealh growth;

e) It is necessary to enhance awareness and facilitate provision of education on mHealth for healthcare professionals, patients and all stakeholders. It is a key challenge to promote, in the proper and understandable way, the knowledge on health and to improve the digital literacy among all partners at the same time.

24. Since the purpose of using mHealth solutions is to manage the user's health including chronic diseases, the provision of accurate information regarding usage conditions, quality and safety is crucial for succeeding in this new area:

a) Personal health data belongs to the category of 'sensitive' personal information under the existing and future EU data protection law, which requires a higher level of protection. There are some views and doubts, that legislation for data protection in the EU places individual right to privacy above the use of such data for the larger benefit of society (such as the use of data concerning health in medical and scientific research), thereby restricting proliferation of innovative mHealth solutions. It is important to clear and solve this problem as fast as possible – preferably during the process of implementation of the General Data Protection Regulation. On the other hand, there are some possibilities that allow using patient's data for research purposes. These options and concrete paths enable the usage of the data under the secure rules. **The work on data in the area of mHealth should be based on facts, rules, and clear interpretations - not on threats, doubts and myths;**

b) We also need to solve the problem of using health data collections (anonymized, masked from individual point of view) for better analysis and dissemination of knowledge on health, proper understanding of regularities and irregularities in health phenomena, which is important for patients own health assessment and which would contribute to making a better diagnosis. The dissemination channels of those kinds of information should be established as neutral platforms for making this knowledge accessible. The problem is to make the secure storages of those data and to have rules for sharing them also across borders. The last thing requires **hard work with the Member States to convince them during the implementation phase of GDPR to be more open for data sharing**, especially for the analytical and research purposes (-also for Biobanking) all over Europe. It will be connected with clear legal options;

c) The proper transfer of data requires significantly better interoperability based on well standardized schemes and functioning also due to transparent rules of portability;

d) Standardising the data definitions (for example, health data v. well-being/recreational data), precise rules for classification of datasets (not necessary related to the personal data), models of ownership and data governance across mHealth solutions are necessary to allow a seamless exchange of data across platforms without excessive administrative burden to innovative mHealth solutions providers as well as to users. It should be also done as fast as possible in the time of implementation of the General Data Protection Regulation;

e) The privacy protection is the fundamental right. A guarantee for high level of data protection is crucial to ensure that mHealth applications can evoke trust of end-users. Both patients and doctors need to be sure that the personal health information that they trustfully enter in mHealth applications will be processed according to applicable regulations and will not be shared with unauthorised parties. **The only owner of the data is a patient,** and only his decisions can change the rules concerning accessibility to the datasets such as a patient's history.

It is obvious and crucial to have the integrated, electronic model of healthcare systems that would function across the EU Members States. It is the long term goal, but on the other hand, now **we need to initiate paradigm shift in the context of the healthcare system, if we want to provide the next generation with a more secure and adequate model.**

4/ mHealth development - the way forward

25. For development we still need:

a) It is crucial to have a developed infrastructure: fast and secure Internet, accessible for everybody and in various geographical locations, with possibilities of super high quality traffic management, ensuring precise (in milliseconds) delivery of data. It means implementing changes going in the direction of 5G, and providing well described specialized services related to the public goods, as e.g. health care goals. We also need the high performance computing infrastructure development for fast processing of data and secure storages, addressed to the healthcare challenges. It will be the foundation of the personalised medicine;

b) It is significant to know, that at the same time we should avoid digital exclusion of certain groups within the society. We need to develop e-skills for every citizen, including elderly. It requires special programs and responsibility. Avoidance of the digital divide is one of the most important challenges of the cohesive society;

c) It is key to have clear rules governing personal and privacy data protection, harmonized in Europe, and connected with the sensitivity of health data to the same extent all over the world. This is not a barrier or a burden, this is the prerequisite for creating the trust, as well as for new relations between patients, doctors, and providers of medical services. It is also important to allow patients and citizens to have effective control over their health data and to use such data to access services across health systems regardless of a provider. Standards are a key precondition for interoperability in this respect. In addition, we need to describe the rules governing the usage of analytical data (anonymized health data) for research and collection of data, that is key to gaining knowledge on trends;

d) It is important to ensure standardization of many technological procedures, not redundant, but adjusted to the needs of clear health condition assessments. The doctors' decisions should be based on comparative evidence and give both sides the certainty and the transparency of procedures adopted. On the other hand, in the case of mHealth solutions we need technical standardization, which will ensure the complex interoperability among devices, systems, applications. It necessary to remember that interoperability in general, requires semantic and technical interconnections;

e) It is significant to establish **a new framework of the mHealth development in order to formulate proper rules in the context of liability requirements.** It is especially crucial because of connections between the results of the work of machines (devices - apps in distance) and the effects of the human work (made remotely based on information coming from various sources). All dimensions of these problems require deep consideration among all stakeholders;

f) It is fundamental to include the technological opportunities into the healthcare system. In less than two decades, the Internet and mobile phones have totally changed our communication methods. Mobile phones have already revolutionized the access to emergency care, and the Internet has proven its usefulness in terms of health-related education, self-assessment of the status and information for patients. Over 100,000 smartphone health apps have been created. Medical use of new technologies has become a fully-fledged field of scientific research. The number of mobile applications is on the rise incorporating coaching, prevention, screening, diagnosis, monitoring, therapeutic education, adaptation of care and orientation on treatment methods. Engineers, developers, bio-statisticians and clinicians work together to develop new forms of eHealth in the broad sense. Telemedicine solutions and mHealth serve the needs of both patients and health professionals. Connected devices are the latest innovation in this ongoing revolution. The increasing miniaturization of sensors and the spread of smartphones have spurred the growth of these new tools, which makes it easier for people to monitor their healthcare data on the go and share it with medical professionals if they choose so;

g) **It is very important to understand how the mHealth solutions can simplify the organisation and order in the area of health** by delivering fast access, modernising the work of clinics and hospitals, increasing orientation on patients in management. This is the way for better and more transparent accountability of services. In addition, mHealth can give us more cost effective business models - not only in terms of savings, but also in terms of improving medical services and the quality of life of the ageing society;

h) It is valuable to understand the key benefit related to the new model of healthcare. The expression "connected health", or "mHealth", has become widespread and means breakthrough that is not just technological, but also social. The Internet and connected devices generate new knowledge for users and lead to the personalisation of care. In this new paradigm, there is an increasing interest in healthy individuals, not only with the purpose of treating or taking care of them, but especially of helping them to manage their health better, being supported by a continuous monitoring;

i) It is important not only to include new technological achievements in the healthcare, but also to integrate existing healthcare models, especially oriented on silver generations with new opportunities given by technologies. It is related to two models: more traditional and more innovative forward-looking frames. The first is based on a strong trend towards products and services providing personal assistance through human interaction supported or enabled by the technology. There are many examples of this trend in Central Europe and the Southern countries. The second is based on a role much more automated services and processes. This model may be founded in Scandinavian, Anglo-Saxon, and continental countries. Both models have to become more personalized and tailored to the patient's needs due to mobile possibilities;

j) **How to finance this paradigm shift still remains a question.** But it should be focused on problems solving. As some experts suggest: 'Long-term financial sustainability rests in the balance of stakeholders' "gives" and "gets" across the value chain". The "get" means the package of services and products constituting the implementation of mHealth solutions, with all improvements, efficiency and reduced costs. The "give" is the perceived price of products, services or payments contributed to the value chain, which is key for the economic side.

There is no doubt we need now to combine efforts of the business and fast developing application market with the opportunities of research financing, experiments founded by European funds coming from the Horizon 2020. We need stronger cooperation and public-private-partnership in the area of mHealth. Furthermore, we should consider how patients can contribute in the transition processes of building the future structure of eHealth in the broad sense, and especially of mHealth.

The fundamental questions are:

➤ Who will be the economic buyer of the future model of mHealth? National Health Systems? If so, will they be complemented by stronger participation of the individuals?

➤ How to develop the discussion on that topic, and consider the fact that in some poorer countries the possibility of generating resources for this paradigm shift will be very limited?

➤ What kind of role should the Member States play?

➤ What is the task for the European Union institutions?

➤ And, finally, how and when will we be able to create the big demand for the mHealth services, which, as one of market forces, can change everything?

k) It is key to know what kind of benefits mHealth can bring to moving towards personalised medicine:

☞ Real-time monitoring of patient condition using sensor networks,
☞ Direct delivery of treatment and care at distance by telemedicine with support from mHealth solutions,
☞ Collection, transfer and analysis of the clinical data, which is extremely important in the context of comparing datasets, their processing and using for recent assessments of the threats in the healthcare area,
☞ Delivery of personalised care,
☞ Delivery of health promotion, information on prevention of diseases and on-the-spot guidance to healthcare professionals and patients.

5/ Recommendations

26. If implemented strategically, systematically and in accordance with the necessary safety and quality safeguards (due to the privacy protection rules and by using anonymization), mHealth can revolutionize health outcomes, providing virtually anyone in possession of a mobile phone with useful health information in real-time. The opportunities inherent in mHealth promote a dialogue among a broad range of actors including the government, patients, medical professionals, industry (ranging from multi-nationals to micro-enterprises), academia, policymakers, NGOs, and civil society partners that will help forge a more strategic and cohesive direction for this field and its great potential. The real challenge is to build the powerful coalition of all possible stakeholders aiming at preparation and implementation of the conditions for this paradigm shift within the healthcare system.

27. The European Commission and various EU Member States need to formulate policies that can drive the adoption of high quality, interoperable and safe mHealth solutions. To accomplish this, Member States will need to collaborate on developing European best practices in order to move more effectively between systems and applications. The role of EU-wide standards and European standardisation in creating scalable and interoperable solutions for citizens is key in this respect. **Those various policies should be oriented on one ROADMAP showing how to achieve the goals with regard to mHealth development and change the whole model of healthcare in Europe** - in the reasonable way, with cooperation among Member States and step by step, at the pace which will be adequate to the challenges and all institutions' readiness for the changes.

28. Raising awareness activities concerning mHealth tools, services, their usage and skills it requires should be undertaken in individual Member States as well as at the European level and should be focused on both healthcare professionals and patients.

29. The facilitative policies aimed at mHealth development need to be supported by a coherent and stable regulatory framework that adequately addresses the key concerns of users over safety and trust. Such framework must ensure proportionate and clear EU rules for data protection and privacy that enable an adequate usage of data in creation of patient--centred and sustainable healthcare and meeting broader public policy objectives. The framework should also allow citizens to access their own health data in a secure and interoperable way across healthcare services and providers to achieve more integrated and patient-centric forms of care.

30. The adequate non legal framework is also needed for mHealth development. It is related to the dissemination of codes of conducts and best practices in many areas, transparent rules for certifications, and - if needed, some guidance prepared at the EU level.

31. **mHealth services must be appropriately positioned during the debate within the Digital Single Market Strategy in order to strengthen an impact on end-users' needs related to many aspects of a digital game changers:** solutions harmonised at the European level, privacy protection, rules for platforms, clear forms of portability, guarantees for cross-border interoperability, new understanding of data ownership, conditions for data sharing, the Big Data development, the Internet of Things growth, ethic challenges related to the robotics appearance, etc.

32. Regulatory clarity relies on the difference between medical devices/applications and recreational/well-being ones. This can be done by updating the current guideline and by setting up an institutionalised consultative structure with the involvement of businesses and all stakeholders.

33. As far as interoperability is concerned, the EU should promote companies' contributing with their technology to increasing standards in order to enhance interoperability between mHealth solutions and healthcare IT, e.g. electronic health records (EHRs), thus helping to support scalability and the launch of fast-to-market products. The role of European standardisation organisations (CEN, CENELEC and ETSI) in achieving EU-wide quality standards for reliable mHealth solutions needs to be promoted.

34. In order to ensure that users are fully informed about the conditions of utilisation of mHealth solutions, new sources (beyond the user manual), using easily accessible means such as a government supported website, are needed. Considering the nature of mobile devices, it would be rare for users to carefully look at the manual before its use. Mobile users usually use the website or the user interface to learn how to use the product. Therefore, a new form of manual or labelling distribution to increase the user's awareness is needed in order to guarantee the safe use. In addition to the effort to find or develop a new method, a campaign at the government level or advertisement regarding the difference between well-being and medical solutions would be beneficial users' understanding of the apps' true nature.

35. For the purpose of eHealth and mHealth development we need to consider the well-designed financial framework. In the mid-term perspective it should be analysed and decided how the mHealth services could be incorporated into the financing and economic models of healthcare systems. **We need to review the reimbursement models and modernize them in line with budgeting telemedicine solutions.** It requires consideration to find the way for making mHealth services available and financed as the part of standard healthcare services provision.

TO-DO-LIST

36. It is important to have a to-do-list in order to prepare to the paradigm shift in the area of healthcare. The major points on that list are:

✖ continuation of the dialogue among stakeholders (permanent form: workshops),

✖ review of the legislative solutions in the area of mHealth: what do we have, what do we need, what kind of framework we need: regulatory and non-regulatory, with a proper distinction - in which areas we need the so called: strong regulation (European regulations, directives, national law) and the, so called soft law (guidance at the EU level, schemes for certifications, code of conducts) - in the model of co-regulation,

✖ monitoring of the implementation of the Code of Conduct for mHealth: after all opinions of stakeholders are known and during the process of usage. It is also needed to promote and disseminate the information about this Code of Conduct - for stronger involvement of all possible partners,

✖ implementation of recommendations after the Green paper on mHealth consultation process,

✖ implementation of the General Data Protection Regulation (in order to improve patients' confidentiality and data security), especially delegated acts focused on precise definitions of health data and possibilities of using anonymized, masked data for research purposes, as well as collecting data to enhance knowledge on trends, symptoms, threats, as the result of data processing,

✖ consideration: how to join the forms of personal data protection with consumers' rights protection in the area of healthcare,

✖ dissemination of know-how on security safeguards by data encryption and authentication mechanisms (to solve the problem of the secure mobile identity). In order to adjust the solutions to new technological possibilities it is necessary to assure security and privacy by design. Because of the sensitivity of personal health data, they should be encrypted both 'in transit' and 'at rest',

✖ preparation of the application plan starting after the finalisation of the work on changes in the medical devices regulation,

✖ assessment of the legislation needed in the area of application of the General Product Safety Directive in the context of mHealth development,

better and much more precise description of the mHealth benefits for patients: (self-health estimation; early warning and identification of the threats; monitoring of the health condition of every patient); processing the data and precisely (answering the question, what data will lead to the personalization of therapies); simple applications for supporting activity (steps, tracking personal information etc.); transmedical solutions (treatment, long distance surgeries, technical and legal conditions under which these are performed; order of access to the doctors; e- prescriptions),

prepare the in-depth analysis of the financial advantages for patients using the mHealth solutions and procedures, as well as on the time saving formulas in the context of physicians and patients relations,

identification of organisational, mental, institutional, legislative barriers of mHealth development,

preparation of the processes of various models of standardization (especially background for unification of the standardized metrics), procedures of certifications and evaluation of the effectiveness of the level at which the review of certifications adjustment should be done (especially related to the mHealth apps),

using the Commission's ICT Multi-Stakeholder Platform as the basis for recommending global standards that could be applicable in the EU,

initiating the cross-border solutions that are key to the improvement of interoperability, establishment of open standards for interoperability, especially for healthcare systems interoperability in the EU (checking the possibilities of healthcare support in the area of interoperability in the EU project - ISA 2, checking what kind of solutions we need at the legislative level and what kind of actions and practical implementations are required). It should be crucial, both at the EU level and in Member States, to ensure interoperability of mHealth solutions by means of the Electronic Health Records. In general, it also requires portability,

in-depth analysis and evidence based descriptions of the risks: liability (app developers should have a clear understanding of their liability when designing mHealth), social approval, governmental capacity to implement all those changes, important for mHealth development,

in-depth analysis oriented on the new possibilities of the financing of the new healthcare model and the transition period from today's solutions to the healthcare delivery of the future. It is important to possess the knowledge on how to combine the savings coming from cost-effective solutions with investments in the quality of the new model: mHealth, eHealth, personalized medicine - in broad sense. The question is how to incorporate the new demand related to the mHealth to the business models of the financing in the health area, including the public forms of financing,

prepare the concrete, multidimensional ROADMAP for this paradigm shift, with the involvement all stakeholders.

37. All those undertakings will not only support creation of a better framework for mHealth development but will also facilitate the growth of the real market demand related to the mHealth services. They will result in speeding up processes important from the patient' perspective enhancing the quality of the personalized services, and from the perspective of the European healthcare systems, which require the paradigm shift. Individual expectations and systemic changes will be combined and will result in efficient care system.

I would like to express my sincerest thanks to all parties involved in the preparation of the Position Paper. The quality of their arguments constitutes a valuable contribution to the content of the Paper and remarks they have made are concerned an important element of the recommendations provided.

The position paper has been drafted with the aim of reflecting insights gained from relevant public sources and discussions with several stakeholders, including the European Commission, the GSMA and the following organisations: