EFA response to the European Commission public consultation on the Green Paper on mobile Health

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and chronic obstructive pulmonary diseases (COPD) patients organisations, representing 38 national associations in 24 European countries and over 400,000 patients. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health.

Visit www.efanet.org for more information.

Executive Summary

EFA is representing people with allergy, asthma and COPD at the European level. **Asthma and allergy** are the most common chronic diseases in children and the leading cause of school absences, emergency department visits and hospitalisations.[1] In Europe almost 30 million of children and adults less than 45 years old have asthma, and around 10% of them have severe asthma, which is difficult to treat and manage. It is estimated that 1/3 of European population will develop asthma, most likely before the age of 20.[2] **COPD** is a progressive disease that affects 44 million people in Europe and is expected by the World Health Organisation (WHO) to become the third leading cause of death by 2030.[3] Studies predict that 1 in every 2 Europeans will suffer from an allergy by 2015. Among all the different types of allergies, respiratory ones represent the most common allergies and currently affect around 20-30% of the European population.[4]

This response was prepared in consultation with EFA membership. Indeed, mHealth is particularly useful for patients with asthma, allergy and COPD as it has the potential of thoroughly improving the management of their diseases and their daily-life activities. In addition to this, asthma and allergy affect both children and adults and therefore, mHealth developed for these diseases is widely spread and used by different age groups.

Answers to specific questions

Question number 1: which specific security safeguards in mHealth solutions could prevent unnecessary and unauthorised processing of health data in a mHealth context?

As underlined in the Commission document, it is unacceptable that health-related apps transmit the data of their users to third companies, especially as patients do not want their health data to be released. Security safeguards are therefore necessary to guarantee that health data is not processed without prior authorisation. This could lead to patients' discrimination in work places and/or their daily-life activities and it cannot be accepted.

Solutions for dealing with the loss of personal mobiles and the eventual dissemination of health data should be found. Passwords should be developed for all apps, but other innovative and more secure systems should be identified. All data should be fully anonymised.

Question number 3: what measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU while complying with legal and ethical requirements?

In order to develop the measures allowing greater use of "Big Data" solutions, firstly, it is essential to point out the main obstacles on the way of "Big Data" potential realisation, and then, to come up with the solutions on how to minimise the arising challenges:

- **Data/information security/privacy:** "Big Data" software generally does not have safeguards from inappropriate access. In case of data that are highly sensitive in terms of patients' privacy,

[1] Erkka Valovirta, *EFA Book on Respiratory Allergies – Raise Awareness, Relieve the Burden*, 2011, available at: http://www.efanet.org/documents/EFABookonRespiratoryAllergiesFINAL.pdf.
[2] European Respiratory Society (ERS), *The European Lung White Book – Respiratory Health and Disease in Europe*, 2013.
[3] Mariadelaide Franchi, *EFA Book on COPD in Europe – Sharing and Caring*, 2009, available at: http://www.efanet.org/documents/EFACOPDBook.pdf.
[4] Erkka Valovirta, *EFA Book on Respiratory Allergies*, cit.

the security of healthcare institutions and regulatory requirements, enterprises must ensure that the data is secure and covered by the same data security policies that apply to the data placed in databases;

- **Ethical implications:** "Big Data" can be useful for both governmental bodies and private companies to support decision-making in many areas, including public health. It can also be used within the scientific domain, e.g. secondary uses of patient data could benefit to investigation of cures and prevention for various diseases. However, very little is understood about the ethical implications caused by use of the "Big Data". It is not clear how to ensure that patients will not be hurt by research process in case their medical data is used for such purposes. To tackle this and similar problems, more attention should be paid to the implementation of accountability and control measures by the EU. Furthermore, patients and their representatives should participate in ethics committees in order to decide on how to use the sensitive data;
- **Competent personnel:** it is crucial to ensure that there are enough of highly competent professionals to deal with administrative tasks related to the development of "Big Data", thus ensuring that patients' security and safety is guaranteed.

Question number 4: are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU framework?

EFA considers that current EU framework is not sufficiently covering safety and performance requirements of lifestyle and wellbeing apps.

Question number 6: please give your reasons on why you do not think so

The Commission staff working document on the existing EU legal framework applicable lifestyle and wellbeing apps summarises the EU legislation applicable to lifestyle and wellbeing apps. EFA considers this document as a comprehensive illustration on why current EU framework do not adequately cover safety and performance requirements of the mentioned apps:

- Some mHealth apps may fall under the definition of a medical device or of in-vitro diagnostic medical device and therefore may have to comply with the safety and performance requirements of directive 93/42/EEC concerning medical devices or directive 98/79/EC on in vitro diagnostic medical devices respectively (and future regulations once they are adopted by the Council and the Parliament and they enter into force). There are **no binding rules in the EU 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 legislations, the Commission's services have issued some guidance that will be continuously updated. It is necessary to clarify if apps have to be considered as in vitro diagnostic or medical devices, as the uncertainty of rules applying may result in less patients' safety. In addition, there is not a harmonised regulation of medical devices at the European level, and therefore in different countries apps may be treated differently;
- It is not yet clear if and to what extent lifestyle and wellbeing apps could pose a risk to citizens' health. However, when placing an app on the market, an app developer needs to know whether he has to comply with any **EU safety requirements**;

- Due to the fact that both the **general products safety directive and the directive on liability for defective products** apply to manufactured products, it is not yet clear if and to what extent they apply to lifestyle and wellbeing apps;
- In addition, it is crucial to develop specific rules concerning use of mHealth applications while travelling (e.g. to decide on **roaming** charges).

Therefore, in general, it is necessary to have a clearer definition of which legislation applies to apps in order for patients to be safe.

Question number 7: is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts?

Yes, there is a need to strengthen the enforcement of EU legislation applicable to mHealth.

Question number 8: in your opinion, why should enforcement be/not be strengthened?

The enforcement should be strengthened in order to enhance and harmonise the development of mHealth and its standards, access and practices in different European countries, which would contribute to a better patients' protection across Europe. However, before enforcing mHealth legislation, the data protection legislation should be strengthened in order to ensure data security, as well as to increase patients' trust in the technology they use.

Question number 9: how can enforcement be strengthened?

Member States play a major role in the direct application of the EU law. Therefore, a determination to enforce laws should be accompanied with an adequate assessment of resources available to achieve the levels of inspection needed for effective enforcement, both at the European and national levels.

The Commission plays an essential role in the law enforcement, thus one of the ways to a successful mHealth legislation implementation is strengthening the Commissions' communication and control channels (e.g. regular meetings with national experts). In case of absent, wrong transposition or incorrect application of the legislation, the Commission can bring the matter before the Court of Justice.

In the Commission Communication "A Europe of Results – Applying Community Law", the following potential tools for more efficient legislation implementation are listed:

- **Increased attention to implementation throughout the policy cycle**: legislation should be clear, simple, operable and enforceable. Therefore, an increased attention should be paid to aspects of implementation, management and enforcement in the development of proposals. Further actions include evaluation and monitoring activities;
- **Information exchange and problem solving**: all the complaints concerning the law should be effectively treated through initial information exchange and cooperative problem-solving;
- **Strengthening dialogue and transparency**: inter-institutional dialogue and greater transparency could contribute to the facilitation of legislation implementation.

We would like to emphasise the **need for patients to be continuously involved in the design and evaluation of mHealth solutions** to ensure that the final outcomes correspond with their needs and expectations and, as a consequence, that they are constantly used and implemented. Indeed, patients are the ones using these applications in their daily life and they know better than others what the things that should be improved are and how to do that. Increased patients' involvement is the path that is now followed by the European Union as several legislative instruments make it clear for

patients' rights to be heard when decisions influencing their health are taken. "Nothing about patients without patients", their expertise and vision should always be requested and taken into account.

Question number 10: what good practice exists to better inform end-users about the quality and safety of mHealth solutions, e.g. certification schemes?

EFA represents patients with allergy, asthma and COPD and, as previously underlined, the use of applications and m-Health is particularly crucial for these groups of people in terms of improving their daily-life. Some of our members have endorsed several apps used by patients with asthma, allergy and COPD with their logo and/or other kind of certifications. Members were involved in the development of the application itself and provided the perspective of those living with the disease and using the app in their daily-life.

Allergytrack is a free mobile app that helps people suffering from allergy to stay on track with their allergic and respiratory symptoms during critical periods and helps measuring the impact of their allergy. The app has been developed by Stallergenes with input from EFA.

Other examples include:

- Allergy UK has developed an application, FoodWiz, to control shopping and diet, which is particularly important for people with food allergy;
- The Dutch Food Allergy Foundation has given input to the 5minuteninfo application, which provides information about food allergy and its implications for the work;
- AsthmaCoach from Asthma Society of Ireland won the Health Innovation Award in 2013 as a tool to keep asthma under control, as well as monitoring pollen in the air;
- The French Asthma & Allergy Association has developed an app, Asthmacrise, for asthmatic patients to help them anticipate and manage an asthma attack;
- The Polish Federation of Asthma, Allergy and COPD Patients' Organisations gave patients' input to MojaAstma, an application that helps to better understand the disease with local information about the weather, dust and air pollution;
- The Danish Asthma and Allergy Foundation developed applications to monitor pollen, Dagens Pollental, as well as to check the level of chemicals in consumers' products, Kemilex;
- Longfonds helped developing applications to measure air pollution, iSPEX, and to facilitate patients with chronic disease self-management of their disease and communication with their health care providers, Longpas;
- The Norwegian Asthma and Allergy Foundation helped developing Pollenappen, a pollen monitoring application with notifications from local areas.

Question number 11: what policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

In order to ensure/verify the efficacy of mHealth solutions, more research is needed. This is particularly true as mobile health has the great potential of benefitting patients' lives in Europe, but at the same time, it is paramount to assess that the right expertise is behind health apps as patient's health may be concerned, and even seriously compromised otherwise.

One of the possible options is evaluation of a particular mHealth solution that was implemented in a certain country. Based on this kind of study, it is possible to develop a good practice database that can be used for further policy formation. Sharing of best practices might be useful not only at the

geographical level, but also when treating different diseases: what resulted in positive outcomes for a disease can be applied to another one.

EFA encourages to specially measure the efficacy of certain health apps for the monitoring of chronic diseases, such as asthma, allergy and COPD, not only because they track symptoms and therefore might entail a different use of medicines, but also because they are used by divergent population groups, like teenagers or seniors. We consider that with regards to mHealth, not only the disease but also the individuals' technological knowledge and performance aggregate to the final result. From a patient perspective, efficacy of mHealth solutions should be ensured by a competent authority, through a certification.

Question number 12: please explain why you think so

mHealth is a developing concept, an analysis and assessment of existing mHealth solutions across the globe could significantly improve efficacy of the prospective mHealth policies in the EU.

Question number 13: how to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?

Although mHealth tools are mainly used by individual patients, a continuous monitoring from healthcare practitioners, especially from primary care, is recommended to guarantee that patients and citizens are correctly benefiting from them. Moreover, creating ad-hoc user communities will be helpful to share experiences, problems encountered and solutions found.

Safe use of mHealth can be then ensured by constant mHealth solutions assessment and monitoring, which can be performed by organisations such as the European Network for Health Technology Assessment; in case the resources of the mentioned organisation are not sufficient to perform this task, another agency specialised on mHealth solutions assessment and control might be established.

Question number 16: do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?

mHealth solutions have the potential to significantly reduce the healthcare expenditures by:

- **Empowering patients** by providing their increased involvement in disease and health management; and therefore contribute to patient-centred care, with supporting follow-up, guided self-management and, most importantly, continuity of care;
- Supporting citizens in making their **lives healthier** by improving lifestyles, by reducing the incidence of disease through education, awareness and behavioral changes and by enabling virtual communities to share and support best practices;
- **Expediting the diagnosis** of chronic diseases in order to limit their severity and associated treatment costs;
- **Administering care remotely** through mobile-based communication technologies that support patient mobility and reduce the need to visit hospitals;
- **Enhancing clinical decision-making** and improving the utilisation of physical and human healthcare resources by providing the system and staff more information and analysis.

As previously mentioned, mHealth solutions have great potential for the lives of patients with allergy, asthma and COPD. Applications have been developed to monitor the level of pollen in the air or the air quality in cities. This information is fundamental for people with allergy and respiratory diseases as, on the basis of it, they will be able to adjust their behaviours and daily decisions, for instance they will

limit physical activities outside or avoid being outside in the peak hours. Other applications with special value for people with respiratory diseases are those detecting signs of exacerbation, as patients will then be able to adjusting medications to prevent their occurrence, or those providing guidance to use inhalers. People with food allergy may use mHealth to check whether the products they are eating or buying are safe, and therefore avoiding even life-threatening events such as anaphylaxis.

Question number 17: please explain. Please upload the evidence you have or provide links to the relevant sources and webpages

According to the study on socio-economic impact of mHealth for the European Union, mHealth could save in total 99 billion EUR in healthcare costs in the EU and add 93 billion EUR to the EU gross domestic product in 2017 if the adoption of mHealth solutions is encouraged. Full report is available here.

The development of mHealth may entail a better and more efficient management of diseases, including follow-up, and an increased integrated care. Innovation may enhance the capacity of healthcare systems to address the challenges posed by both chronic diseases and the related complications for autonomy in daily life among patients and their caretakers. Indeed, these innovative instruments may facilitate the access to and the provision of care, contribute to the empowerment of patients, reduce hospital stays, emergency and doctors' visits, improve communication and cooperation between the patients and the healthcare professionals, ensure constant monitoring of the disease and continuity of care, and stimulate better compliance and adherence to treatments. The use of these innovative solutions may provide timely and qualified input for decision-making to patients, increasing their quality of life, reduce their need to go to hospitals and specialists, and enhance communication with their healthcare professionals to improve their health literacy and subsequently empowerment.

Question number 18: what policy action could be appropriate at EU and national level to support equal access and accessibility to healthcare via mHealth?

To ensure equal access to mHealth solutions, it is worth to think about reimbursement or funding mechanisms that would cover patients for the cost of mHealth solutions and associated devices, especially among the low income group.

Furthermore, older people might not have enough technological knowledge on how to use mHealth solutions; therefore, educational programmes should be provided by the local healthcare institutions. To guarantee an optimal use of innovative solutions by the public (patients, informal/family carers and all healthcare professionals, from nurses to specialists), it is necessary to develop training/coaching programmes for patients on their use, as well as to raise awareness of their availability and benefits. Regulators and healthcare professionals need to think innovatively, but at the same time we believe that we should never leave behind those people that will not be able to use these kind of apps.

Question number 19: what do you think should be done in addition to the proposed actions of the eHealth Action Plan 2012-2020 in order to increase interoperability of mHealth solutions?

In addition to the proposed actions, the regulation on interoperability standards should be developed.

Question number 20: please explain why

Current absence of such regulation limits efficient applicability of solutions and devices capable of working with each other.

Question number 21: do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records?

Yes.

Question number 22: if you think so, please explain who should work to ensure interoperability and how should this be done?

Better interoperability at the European level will always result in better income for patients.

Question number 26: what recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription on mHealth solutions?

In addition to other experts, mHealth manufacturers and healthcare professionals should involve patients as they are the ones using the devices in their daily life. As previously emphasised, the involvement of patients will ensure that the final outcomes correspond to their needs and expectations and, as a consequence, that apps are constantly used and implemented.

Question number 27: what specific topics would you provide for EU level research, innovation and deployment priorities for mHealth?

Barriers encountered by users and how to overcome these should be further explored by EU research.

Question number 28: how do you think satellite applications based on EU navigation systems (EGNOs&Galileo) can help the deployment of innovative mHealth solutions?

These applications would be particularly helpful for patients as they can provide the localisation of hospitals, pharmacies, etc. when needed.

Question number 29: which issues should be tackled as a priority in the context of international cooperation to increase mHealth deployment and how?

Data protection related issues should be tackled as a priority, as health data in the EU is a sensitive issue and requires a high level of protection.

Question number 30: please explain why do you think so

Data protection is patients' fundamental right and it is important to ensure that this right is ensured in the context of national and cross-border healthcare. Data safety is key to smooth processing of health data and it is essential for the good functioning of healthcare services, patient's safety and research, therefore data safety issues should be a priority for international cooperation within mHealth field.

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