

## **EDITORIAL**

### **E-health and m-health: Great potentials for health and wellbeing, but also for harmonization and European integration in health**

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Health has never been an European Union (EU) priority like agriculture, research, ecology or food safety and still remains to be first of all, if not exclusively, the responsibility of member states (MS). From the EU perspective, health is the crosscutting policy sector dominated by many other policies, especially by the “hard law” regulations of the Internal Market. In the preceding two volumes, the South Eastern European Journal of Public Health (SEEJPH) published an admirable lengthy article by Hans Stein and equally splendid supplemented commentary by Bernard Merkel recounting and evaluating developments of the EU’s health policy from the 1992 Maastricht Treaty (and even from earlier) to the present-day state and future perspectives (1,2). Although health still has very weak basis in the EU legislation, it has evolved from “non-topic” into a key area of the EU economic policy (1), but despite a growing competence “*the unfinished story of the EU health policy*” is slowly moving from declarative to operational phase in developing framework for circulation of health goods and related items within Europe and beyond (2).

In his commentary, Dr Merkel has summarized changes in treaties and other regulations from 1971 (Directive on pharmaceuticals and Regulation on coordination of social security systems providing rights to health care to workers in other EC countries) through the following milestones: (i) the Article 129 of the Maastricht Treaty that for the first time introduced health although in a very weak manner; (ii) the 1997 Treaty of Amsterdam that extended the public health article and introduced the new one (Article 152) including for the first time a few specific areas related to blood and organs, some veterinary and phytosanitary areas and other things, and; (iii) finally, the 2007 Lisbon Treaty with inclusion of medicinal products and medical devices but also incorporating the Charter of Fundamental Rights of the EU including the right to access health care (preventive and curative, Article 35 of the Charter) (3).

Having in mind also the common currency introduced and spreading since 1999, the conclusion that Single Market will finally have an impact on health and health policy stands up. On the other hand, Charter of Fundamental Rights of the EU (proclaimed in the year 2000 but being put in the new legal environment since it became formally binding by the Lisbon Treaty in 2009) has declared in its Article 35 in addition that “*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*” prior than this principle became known as Health in All Policies (HiAP) during the Finish EU presidency in 2006.

According to what has been mentioned above, population health and organization of health system (including health insurance) has always been and remains a national responsibility. At the same time, the EU member states (as well as accession candidates and potential candidates) were shaping their health policies, implementing activities and monitoring systems directed by recognized international organizations such as WHO and OECD (and, more recently, the EU) and also used their support in responding to health threats from communicable diseases and disasters, as well as in combating the growing burden of non-communicable diseases.

Finally, Single Market principles are going to enter health sector somehow through “back-door” via instruments such as Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare that came into force on 25<sup>th</sup> October 2013 (4), up to now without a great success, but with potential to improve access to healthcare services and harmonize their quality within the EU member states and push them to cooperate closer in establishing of health networks in order to meet patients’ expectations.

Another very important opportunity for European integration is influencing and penetrating health sector from a much broader perspective of fast developing communication technologies.

A Digital Agenda for Europe Initiative was selected as one of the seven flagship initiatives supposed to be crucial for obtaining the targets of Europe 2020 strategy for smart, sustainable and inclusive growth (5). The adoption of EUROPE 2020 strategy in 2010 was followed by “E-Health Action Plan 2012-2020” (6), a new one after the previous adopted in 2004 (7), and “A Digital Single Market Strategy” for Europe which was adopted in May 2015 after the new European Commission elected in 2014 set up ten priority policy areas in its Agenda for Jobs, Growth, Fairness and Democratic Change including the priority to create “a connected digital single market” listed as No. 2 priority by Jean-Claude Juncker in his Opening Statement speech before the European Parliament delivered on the 15<sup>th</sup> of July 2014 (8,9). It is expected that the creation of digital single market will enable the creation of new jobs, notably for younger job-seekers, and a vibrant knowledge-based society. Enhancement of the use of digital technologies and online services was proclaimed as a horizontal policy, covering all sectors of the economy, as well as the public sector including health, and common European data protection rules were seen as a necessary prerequisite.

Facts about the “Digital Agenda for Europe Initiative and Digital Single Market (DSM) Strategy” are available at the respective web-site (10), where we can also find new information and follow developments and public consultations on selected topics of interest.

The “Digital Agenda for Europe Initiative” proposes to better exploit the potential of Information and Communication Technologies (ICTs) in order to foster innovation, economic growth and progress. It consists of the following seven pillars:

- i. Digital Single Market
- ii. Interoperability & Standards
- iii. Trust & Security
- iv. Fast and ultra-fast Internet access
- v. Research and innovation
- vi. Enhancing digital literacy, skills and inclusion
- vii. ICT-enabled benefits for EU society

A “Digital Single Market” (DSM) is one in which the free movement of persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence.

At (10) we can find definitions of e-Health and m-Health as well as information on what is going on in digital society including the public consultations launched on respective topics.

Information and Communication Technology for health and wellbeing (e-health) is becoming increasingly important to deliver top-quality care to European citizens and includes informatisation of health care systems at all levels (from local through institutional and regional to European and global level including use of tele-consultations and telemedicine. Mobile Health (m-health) is a sub-segment of e-health and covers medical and public health practice supported by mobile devices. It especially includes the use of mobile communication devices for health and wellbeing services and information purposes, as well as mobile health applications. Particularly important are policies for healthy and active ageing with help of ICT and use of mobile applications for health and wellbeing including home care monitoring devices (wired and mobile). There are already more than 100,000 applications for health, fitness and wellbeing obtainable for different mobile platforms, the majority of which are designed for Apple IOS and Android smart phones.

The European Commission often consults with stakeholders on a number of subjects and such consultations can be found on the pages of Digital Agenda for Europe (10). The Commission launched a public consultation on the Green Paper on mobile health (11) on 10th of April 2014.

The Green paper on mobile health covered broad scope of m-health potential for both, healthcare and market. Main potential for healthcare are seen in (i) increased prevention and quality of life approach, (ii) more efficient and sustainable healthcare, and (iii) more empowered patients.

Having in mind that the healthcare systems' organization is a national competence Green paper focused on cross-border European-wide issues and on possible coordinated actions at EU level that could contribute to the scale-up of m-health in Europe by putting 11 issues at stake:

1. Data protection, including security of health data
2. Big data
3. State of play on the applicable EU legal framework
4. Patient safety and transparency of information
5. m-health role in healthcare systems and equal access
6. Interoperability
7. Reimbursement models
8. Liability
9. Research and innovation in m-health
10. International cooperation
11. Access of web entrepreneurs to the m-health market

The Commission also published a staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps, aiming at providing simple guidance to application developers on EU legislation in the field (12) and invited the views of stakeholders like:

- regional and national authorities e.g. health ministries, authorities dealing with medical devices/data protection
- health professionals, carers, health practitioners, medical associations
- consumers, users of m-health apps, patients and their associations
- web entrepreneurs
- app developers and app stores
- manufacturers of mobile devices
- insurance agencies
- sports centres, health clubs, and the like.

Consultation was open for more than three months during which stakeholders responded to 23 questions on a wide range of themes: data protection, legal framework, patient safety and transparency of information, m-health role in healthcare systems and equal access, interoperability, reimbursement models, liability, research & innovation, international cooperation and web entrepreneurs' market access. A total of 211 responses were received and summarized in the published report (13).

Besides the great potential for health and wellbeing, there are some concerns, as well. The safety of mobile health solutions (and of some lifestyle and wellbeing applications, too) is a main cause for concern, explaining the potential lack of trust. There are reports pointing out that some solutions do not function as expected, and may not have been properly tested or in some cases may even endanger people's safety. That is why on both sides of the Atlantic, regulations for medical devices including software applications are established and continuously updated (14-16). It is beyond the scope of this article to discuss the importance

and the need of certification of e-health and m-health devices and software, but health professionals must carefully take this issue into account and stick to guidelines and recommendations issued by regulatory agencies and bodies as those cited.

Undoubtedly, e-health and m-health have a large potential for health and wellbeing through empowering of patients and enabling them to take responsibility for their own health while reducing the ever-growing healthcare costs. At the same time, health professionals and students need to be educated and trained to evaluate such applications or at least to take into account their limitations. My personal experience has shown that medical students are capable to test m-health applications and understand the need for validation and certification of such applications. They successfully prepared a seminar in Medical Informatics using their own smart phones. Within the same course students received assignments to read, understand and present EU directives, charters and other documents (e.g. 3,4,6,11,14,16) in order to become acquainted with the European integration in health.

Health systems in the EU are facing the common challenge of a rise in chronic diseases as a consequence of our increasingly ageing population. Vytenis Andriukaitis, the EU Commissioner for Health and Food Safety, entitled his column in August 2015 issue of the European Journal of Public Health “How the eHealth can help with Europe’s chronic diseases epidemic” (17). Quotes from this article are presented below:

*“As a former medical doctor, I am fascinated with innovative solutions that are part of today’s medical toolbox. I would like to highlight eHealth in particular. The more I learn about eHealth, the more convinced I am that it can enable better health, better and safer care for citizens and more efficient and sustainable healthcare systems. eHealth and mHealth can deliver more tailor-made, ‘citizen-centric’ care, more targeted and effective therapies, and help reduce medical errors.”*

Good to hear that eHealth Network has adopted the guidelines on electronic prescriptions needed for their cross-border exchange and progress in interoperability:

*“Although the deployment of eHealth is the responsibility of Member States, the EU adds value in many ways. The eHealth Network set up under the cross-border health care Directive provides a forum for cooperation, support and guidance for speeding up the broad use of eHealth services and solutions. Facilitating interoperability and safe and efficient handling of electronic health data across national and organizational boundaries is a key issue. The eHealth Network has already adopted Guidelines on cross-border exchange of Patient Summaries and prescriptions. These Guidelines encourage the adoption of eHealth applications at national level.”*

Guidelines on ePrescriptions dataset adopted by eHealth Network (18) are intended to be complementary to the Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the validation of medical prescriptions issued in another Member State (19), but also as another document for implementation in the near future.

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