

On 27 April 2013, the CPME Board adopted the "CPME Statement on the Communication from the Commision to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on the eHealth Action Plan 2012-2020 : innovative healthcare for the 21st century (COM(2012) 736 final)"

## CPME Statement on the "eHealth Action Plan 2012-2020 : innovative healthcare for the 21st century"

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> CPME is registered in the Transparency Register with the ID number 9276943405-41. More information about CPME's activities can be found under www.cpme.eu



CPME welcomes the European Commission's communication setting up an "eHealth Action Plan 2012-2020: innovative healthcare for the 21<sup>st</sup> century."<sup>2</sup>

EHealth is progressively becoming part of our lives. Both patients and physicians are facing a changing and challenging environment in the healthcare sector, due to the increased use of eHealth tools. We believe that eHealth should be a tool in modernisation of the health care sector. CPME welcomes the use of eHealth solutions where they produce potential benefits for patients and physicians.<sup>3</sup> These include:

- Facilitating access to health services in remote or under serviced areas, as well as reducing waiting times for medical procedures;

- Improvement in the quality of the health service delivery and patient safety, eg. for patients with chronic or rare conditions. EHealth is a way to better empower patients;

- Better working conditions, ie. the facilitation of the physicians' work, greater mobility of physicians in a cross border context, is another important benefit for CPME;

- If implemented and used appropriately, eHealth solutions might help increase efficiency, eg. by reducing duplication of tests and procedures and improving cooperation between organisations.

This being stated and building on previous statements<sup>4</sup>, CPME would like to highlight the following points for consideration:

• A patient-centred approach

It is necessary that the development of eHealth is not primarily driven by economic and technological interests. The implementation of eHealth solutions should be based on effective tools, which have been proved to enhance clinical results and improve the quality of treatment and care provided by health professionals. Currently, the development of eHealth applications, e.g. for elderly people or self-management of chronic disease, constitutes a growing market. It is important that the developments of these applications are not only industry driven. CPME therefore recommends that further development of patient-centred applications should be encouraged and that the best interest of patients be always kept as the principle driving force of eHealth development by policy makers.

<sup>&</sup>lt;sup>2</sup> <u>http://ec.europa.eu/information\_society/newsroom/cf/itemdetail.cfm?item\_id=9156</u>

<sup>&</sup>lt;sup>3</sup> CPME took part in the European Project "Chain of Trust" led by the European Patients Forum. The final report published in January 2012 elaborates recommendations which will be valuable and decisive tools for policy makers in the future when looking for sustainable eHealth implementation at national and European level. The final report is available <u>here</u>.
<sup>4</sup> CPME adopted in 2011 the "response to the public consultation on the eHealth Action Plan 2012-2020" (link to document)



• Involvement of the medical profession

It is important that the medical profession is included in these developments from the very beginning and on a continuous basis. EHealth solutions should indeed benefit the medical work; therefore, they should be adjusted to the needs of health professionals. Electronic health records, for example, are important to physicians' daily work, this requires that physicians are included in the development process of these systems. Furthermore, evaluation of the applications when purchased and their usability in the daily practice is key.

• Training and structural funds

In its response to the public consultation on the eHealth Action Plan, CPME emphasised the importance of setting up tailored and regular trainings at the workplace for health professionals, hence making eHealth part of continuous professional development. This would help guarantee the acceptance of these new technologies by health professionals. Education, training and support should address the use of technology. CPME welcomes in general the leverage of the structural funds for the deployment at EU level of innovative tools and services foreseen in the proposed Action Plan. CPME suggests that these funds are also used for projects setting up training activities for health professionals, including physicians.

Interoperability

CPME welcomes the future publication by the European Commission of an eHealth Interoperability Framework. The lack of interoperability in systems and services, e.g. electronic health records, patient summaries and emergency data sets, is indeed a barrier to further development of eHealth in Europe. While interoperability would need to be achieved at local, regional and European levels, CPME would like to recall that the mechanisms proposed within the Framework should respect the principle of subsidiarity enshrined in Article 5 TEU. Following the conclusions of the eHGI on semantic and technical interoperability<sup>5</sup>, the measures proposed should not interfere with Member States' competences in eHealth. These measures should build on ICT infrastructures already existing in the various Member States. We believe that standardisation of information and harmonisation of definitions based on existing practices are important conditions for interoperability of eHealth systems and services.

Additionally, there is a current lack of interoperability between applications that patients may use and those used by the healthcare professionals. Making these applications compatible would support both patients – to be better active in treating their conditions - and physicians – in communicating with their patients.

<sup>&</sup>lt;sup>5</sup> Discussion Paper on semantic and technical interoperability, 22 October 2012, <u>http://ec.europa.eu/health/ehealth/docs/ev\_20121107\_wd02\_en.pdf</u>



• Legal certainty

CPME welcomes the European Commission Staff Working Document on the applicability of the existing EU legal framework of telemedicine services<sup>6</sup>. CPME believes European guidelines could strengthen legal certainty, in particular in a cross border context. Issues such as liability and data protection, reimbursement, legality and financing of online medical services, and online pharmaceutical information and product supply, is decisive to be addressed. In a cross border context, physicians have to be sure that a medical service supported by eHealth is legally viable. Indeed, because of different implementation approaches in the Member States, the referring physician does share the responsibility for how the data is collected, held and shared in the Member State of treatment. In this regard, CPME issued in November 2012 a statement on the Proposal for a Regulation on the General Data Protection Directive 2012/011 (COD)<sup>7</sup>. However, because legal uncertainty is currently prevailing in many different areas, it is presumed that most physicians do not wish to have this kind of responsibility and might not always feel confident enough to use eHealth tools. EU guidelines could provide clarity and reassurance for health professionals.

• Security

Legal certainty and security are also enhanced by the secure use of identification, authentication and authorisation procedures. CPME notes the work being undertaken on the draft Regulation on eID by the Article 14 eHealth Network, with the advice of the eHealth Governance Initiative<sup>8</sup> of which it is an active part. Under the proposed regulation, which deals with "on-line" identification and authentication of individuals, the relevance to eHealth is in the secure identification of patients whose electronic records may be transferred across borders to support either planned or emergency care. CPME is aware of the proposal to "notify" identifiers that are in use within one Member State to be recognised by another Member State when identifying patient data for cross-border transfer. CPME insists that this process must provide adequate security of patient data, and avoid data leakage.

• Ethics

Appropriate data protection and patients' consent rules need to be ensured with the emphasis on an ethical approach, please see again the CPME latest statement on the Draft General Data Protection Regulation 2012/011 (COD)<sup>9</sup>. Confidentiality between patient and physician is a condition for maintaining trust in the system and the processing of sensitive data. The implementation of patients' data protection rights differs between Member States, which leads CPME to raise awareness towards the introduction of an ethical code of practice

<sup>&</sup>lt;sup>6</sup> <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF</u>

<sup>&</sup>lt;sup>7</sup> CPME Statement on the Proposal for a Regulation on the General Data Protection Directive 2012/011 (COD) (<u>link to</u> <u>document</u>)

<sup>&</sup>lt;sup>8</sup> Draft Regulation on "electronic identification and trust services for electronic transactions in the internal market" (2012/0146 COD)

<sup>&</sup>lt;sup>9</sup> CPME Statement on the Proposal for a Regulation on the General Data Protection Directive 2012/011 (COD) (<u>link to</u> <u>document</u>)



for cross-border activities, including eHealth, however, without prejudice to the principle of subsidiarity.

• "mHealth and wellbeing applications"

CPME acknowledges the proposal by the Commission to adopt a Green Paper on mHealth and wellbeing applications by 2014. This is indeed a timely decision, since these new "apps' " develop at an extremely rapid pace, while no current legal clarity regarding their use is provided. CPME will be following very closely the Commission's steps in this dossier and is prepared to provide its medical expertise.

• Costs implication of research and innovation

CPME welcomes the proposals foreseen by the European Commission to support research and innovation under "Health, demographic change and wellbeing" of Horizon 2020 and in the framework of EIP AHA. It is necessary that all eHealth research and innovation programs take into account cost implications, both for patients and physicians. EHealth technologies often require high development costs, while patients and physicians might not be in a position to support these costs. In addition, industry will benefit from the provision of development funds and a fast-track approval mechanism for new devices. In some Member States, e.g. the UK, a large percentage of physicians are employed; therefore, the costs will not directly bear on them. However, in other Member States where most of the physicians exercise in free practices, the costs will be borne by them, by the sick funds and as well by the patients. Either way, investment in eHealth will be costly for patients, physicians and healthcare providers. In times of financial crisis when healthcare systems all over Europe suffer from decreasing spending, cost implications and sustainable provision of eHealth solutions are all the more important.