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On 17 September 2015, the CPME adopted the 'CPME recommendations ahead of trilogue negotiations on the General Data Protection Regulation (2012/0011(COD))' (CPME 2015/087FINAL)

CPME recommendations ahead of trilogue negotiations on the General Data Protection Regulation (2012/0011(COD))

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[1].

In healthcare, data protection is critical to guarantee patients' right to confidentiality. Patients' data contain particularly sensitive information and therefore require the highest possible level of protection. CPME supports the approach of the European Commission to strengthen and harmonise, by means of a Regulation, the currently applicable data protection framework. Ahead of trialogue negotiations on the General Data Protection Regulation (2012/0011(COD)), CPME proposes the following recommendations:

- CPME calls on the negotiators to **amend the definition of 'Data concerning health' in Article 4.(12) as follows:** *'data concerning health' means data related to the physical or mental health of an individual,* ***or*** *which reveal information about his or her health status* ***or data which has been utilised to reveal information about an individual's health status.***
  The suggested definition would be broad enough to also cover mobile health ('mHealth'). Most of the mobile applications currently on the market have a recreational or wellbeing purpose. They collect and process data which by nature are not defined as health data, eg. data concerning diet, sleep, lifestyle choices or physical activity. Although these data are not 'health data' by nature, they may reveal information about the health status of the individual, ie. provide sensitive information. In the context of defining 'data concerning health', it is not simply the nature of the data but what the data is being used for that should be considered. With this

[1] 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

extensive understanding, these situations would be covered. Furthermore, the definition would appear to be in line with the approach of the European Court of Justice (ECJ) which held in the Lindqvist case (C-101/01, Slg. 2003, I-12971, No. 50) that *"(i)n the light of the purpose of the directive [95/46/EC], the expression 'data concerning health' used in Article 8(1) thereof must be given a wide interpretation so as to include information concerning all aspects, both physical and mental, of the health of an individual."*

- CPME calls on the negotiators to **support Commission's and Parliament's approach to maintain the explicit indication in the definition of 'Data subject consent' (article 4.(8)).** In the case of mHealth mentioned above where sensitive information may be processed, it is all the more important to ensure that the consent given is of the highest possible quality level. In the context of the direct provision of care or treatment, this explicit indication would not be required as specific exemptions are foreseen in Article 81.1(a) of the Commission's proposal and article 9.2(h) of the Council's general approach. It is indeed presumed that a patient seeking/receiving care or treatment implicitly agrees for his data to be processed by his doctor, and if needed, by the healthcare team, for the care or treatment purposes.

- CPME calls on the negotiators to **maintain the Commission's original approach towards medical research and support the recommendations of the European Data Protection Supervisor (EDPS) in relation to Articles 81 and 83**[2]**. In particular:**
  - ✓ **CPME calls the negotiators to support the following EDPS amendment to Article 81**: *'2. In the case of point (d) above the processing shall be carried out subject to the additional conditions and safeguards set forth in Articles 83 and 83a, and on the basis of the consent of the person concerned or some other legitimate basis laid down by law, such as, in particular, research that serves a high public interest, if that research cannot possibly be carried out otherwise.'*
  - ✓ **CPME calls the negotiators to support the following EDPS amendment to Article 83**: *'(b) appropriate technical and organisational measures are taken to protect the rights and interests of the data subjects, which must, in particular, effectively ensure that the data cannot be used in support of measures or decisions affecting specific individuals'*.

  Medical research has huge societal benefits and is essential to maintaining and enhancing the health of a population. It is equally essential that the individuals' interests are protected through strong ethical safeguards and reliable governance structures, such as independent research ethics committees and other independent review boards entitled to oversee such processes, or in the UK the Confidentiality Advisory Group. Although the Data Protection Regulation might not be the legal instrument to address ethical questions posed by scientific research, it should provide a proportionate legal framework enabling valuable medical research to progress whilst

[2] Annex to Opinion 3/2015: Comparative table of GDPR texts with EDPS recommendations (27 July 2015). EDPS opinion 3/2015 'Europe's big opportunity - EDPS recommendations on the EU's options for data protection reform' (27 July 2015).

maintaining existing standards of confidentiality and public trust. The EDPS amendments to Articles 81 and 83 appear to create such a framework.

- CPME calls on the negotiators to **support Council's approach regarding the data protection officer (DPO) and the data protection impact assessment.** The appointment of DPOs and the conduct of impact assessments should not create unsustainable burden for doctors, notably when exercising in small medical practices with limited staff resources. The European Parliament's proposal to designate a DPO and carry out an impact assessment when the processing of data relates to more than 5000 data subjects during a consecutive period of 12 months would be significantly costly and potentially unsustainable. The solution proposed by the Council in article 35.1., whereby the decision to appoint a data protection officer is kept non-mandatory and left to national subsidiarity, would appear a more practical and flexible option. Equally, the framework proposed by Council in relation to the impact assessments would also appear more favourable. According to article 33.2. this requirement would only apply to data processed on a large scale and would exclude the cases where the data is processed by an individual bound by professional secrecy, such as a doctor, as highlighted in Recital 71 of the Council.