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On 16 May 2013, the CPME Executive Committee adopted the " CPME Statement on the Report by Jan Philipp Albrecht on the General Data Protection Regulation 2012/0011(COD) and the subsequent LIBE amendments"

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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].

[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

1/ Consent

- Definition

CPME welcomes the clarifications brought to the notion of consent by the Rapporteur and the MEPs through their various amendments. In the context of healthcare, processing medical data is necessary to guarantee the patient the best medical treatment possible. However, a clear distinction needs to be made between primary and secondary use of medical data. The primary use of medical data refers to the patient data being shared with the treating physicians and among the healthcare team. The secondary use of data refers to the data used for example for scientific research or insurance obligations.

Primary use of health data

The necessity for consent to be explicitly given by the data subject - according to which either a written or oral statement or a clear affirmative action is needed – might be difficult to obtain in the context of primary use of health data in addition to the agreement of being treated, e. g. when a physician needs to share a patient's data within a defined healthcare team. The current notion of express consent apparently covers unambiguous actions as well (see Art. 29 Working Party[2]) which would better accommodate the primary use of health data.

CPME therefore welcomes Amendment 412 by MEPs Sarah Ludford and Charles Tannock, which stipulates that the act of seeking and agreeing to health treatment should be considered as consent of the subject for his data to be processed. CPME also welcomes the approach of Amendment 416 by Nathalie Griesbeck, but would recommend it to be slightly rephrased. The current wording might be misleading since the decision to seek medical care is usually understood as an "implicit" agreement for personal data to be processed; using the term "explicit" would create confusion.

Secondary use of health data

When it comes to the identifiable health data for secondary use, CPME is of the opinion that explicit consent - according to which either a written or oral statement or a clear affirmative action is needed – should be sought. In this context it is even suggested that a written statement should be received. The patient indeed needs to agree in writing with his data being used for other purposes than the direct provision of care.

[2] http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2011/wp187_en.pdf

Furthermore, Article 25 of the World Medical Association Declaration of Helsinki, states that *"For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee."* The draft regulation should reflect the approach of Article 25 of the WMA Declaration of Helsinki.
CPME agrees that medical research can in some cases require specific and more flexible provisions regarding consent. "Broad consent" has been introduced by some MEPs as a possibility to avoid impeding the conduct of research (Amendments 2985, 2987, 3054, 3069, 3072, 3079, 3089, 3094, 3095 by MEPs Sarah Ludford and Charles Tannock).

CPME would recommend that before introducing notions of consent, MEPs should first consider what is identifiable data and what is not. CPME considers broad consent, as proposed in these amendments, an unclear concept and should not override the need for informed consent at the present time.

- Significant imbalance

CPME raised concerns regarding the vague notion of "significant imbalance" contained in Article 7(4). In a treatment context, speaking of "significant imbalance" might be understood as an imbalanced relationship between the patient and his treating physician. The patient could evoke a "significant imbalance" to declare the consent given void.

CPME therefore welcomes the deletion amendments 983 to 988 by which any misinterpretation is avoided. Should a compromise be sought between the rapporteurs and the shadow rapporteurs, CPME would advise to introduce the notion of coercive relationship as suggested in amendment 994 by MEPs Sarah Ludford and Charles Tannock. Amendment 994 specifies that a specific exemption should be provided in the context of the patient-healthcare provider relationship. The notion of healthcare provider is very broad; it includes health professionals, but also health institutions, eg. hospitals and care centres. CPME would therefore recommend this exemption to be more precise and to only refer to the patient-physician relationship in the context of treatment provision.

2/ Right to be forgotten/Right to erasure

- Clarifying Article 17(3)(b)

CPME agrees with the numerous amendments seeking to replace the "right to be forgotten" by the "right to erasure". This will bring legal clarity for the sake of the data subject's right. CPME has no objection to the change of terminology as long as it does not negatively impact the exceptions to this right. Health data should be exempted from this right for purposes of preventive or occupational medicine, medical diagnosis, provision of care or treatment, or the management of healthcare services as stipulated in Article 81 of the regulation.

CPME therefore welcomes the clarification brought to Article 17(3)(b) by Amendments 1431, 1432 and 1433.

- Confidentiality and liability obligations

In the context of medical treatment, the retention of data concerning health is an absolute necessity. It is also a matter of liability (eg. outside inspections, complaint procedures, identification of remains with x-rays for example) The proposed regulation foresees exceptions to the erasure of data concerning health for purposes of legal obligations imposed by national laws, eg. obligation for the practitioners to document the treatments provided (Article 17(3)(d)), and for purposes of proof, eg. in the case where the practitioner is challenged in Court (Article 17(4)(b)).

CPME welcomes the Amendments tabled to clarify this in other parts of the regulation, such as amendment 2975 by MEP Philippe Juvin.

CPME is however concerned with the suppressive amendments 1438 and 1439 tabled by MEPs Alexander Alvaro and Dimitrios Droutsas to Article 17(3)(d). The derogation foreseen to the erasure of data for purposes of legal obligations should be kept as such.

With regard to Article 17(4)(b), should a compromise be sought between the rapporteurs and shadow rapporteurs, CPME would advise to support amendment 1458 by MEP Axel Voss. This amendment is comprehensive enough to cover any kind of legal challenge of the controller in Court.

3/ Delegated Acts

CPME acknowledges the numerous suppressive amendments to the delegated acts foreseen in Articles 33(6) - impact assessment and 35(11) - data protection officer. CPME raised concerns about the economic and administrative burdens the implementation of impact assessments and data protection officers would entail for small and medium sized medical practices.

CPME would agree in principle with not delegating powers to the European Commission in this area. However, whether the technical criteria and conditions be specified through delegated acts or by other means, CPME would reiterate its concerns that these measures might constitute heavy burdens for physicians practicing in small practices.

CPME would therefore advise the rapporteur and the shadow rapporteur to consider small and medium sized practices since they do not have neither the financial nor the human resources to carry out impact assessments to and benefit from the services of a data protection officer.

4/ Other remarks

- Definition of "genetic data"

CPME acknowledges the changes introduced to the definition of "genetic data". CPME supports the introduction of the definition of the United Nations International Declaration on Human Genetic Data.

CPME supports amendments 772, 774 and 776.

- Definition of "data concerning health":

CPME strongly objects amendment 783 by Louis Michel.

Excluding from this definition the provision of health services entails the risk of lowering protection standards for patients. In the long run, this might negatively influence patients' trust in health care providers. Be this amendment adopted, the information related to a medical treatment would as a consequence not be considered as health data. This would lead to a two-level regime where the health status of a patient would be considered as "health data" but the provision of treatment would need to answer other legal requirements; this would definitely make no sense.