COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AD/Brd/24112012/064_Final/EN

On 24 November 2012, the CPME Board adopted the "CPME Statement on the Proposal for a Regulation on the General Data Protection Regulation 2012/0011(COD)" (CPME 2012/064 FINAL)

**CPME Statement**
**on the Proposal for a Regulation on the General Data Protection Regulation**
**2012/0011(COD)**

*The Standing Committee of European Doctors (CPME) aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union. CPME represents the national medical associations of 27 countries in Europe and works closely with the national medical associations of countries that have applied for EU membership as well as specialized European medical associations.*

CPME welcomes the European Commission's proposal for a new data protection Regulation, which aims at updating the existing framework (Directive 95/45/EC) dating from 1995.

**The CPME congratulates the Commission for having chosen a Regulation to amend the existing legal framework on data protection**. The existing Directive was transposed into national legislation in 1995, resulting in different national laws since then. Harmonization in the form of a single and directly applicable instrument as the Regulation is welcomed in order to ensure legal certainty and consistency across the EU market.

**The CPME supports the Commission in its objective to introduce the highest level of protection for the treatment, storage and transmission of citizens' data, particularly those relating to health and medical data**. The patient-doctor relationship is built on the premise of confidentiality and trust. All data contained in medical records (paper version and/or e-records) should therefore be considered to be particularly sensitive data and must be afforded the highest possible level of protection in order to ensure that these key principles are upheld.

Paired with the need to adopt the strictest security standards for health data protection, CPME fully agrees with the classification of data proposed by the Commission, whereby **genetic data would be considered also as particularly sensitive data.**

In the context of the provision of cross-border healthcare, as reflected in the Directive 2011/024/EU on patients' rights in cross-border healthcare, the implications for the security of patient data reach a new dimension. A particular problem for doctors involved in transferring data from one jurisdiction to another is the uncertainty about how data will be handled upon reception. While the proposed Regulation introduces greater clarity and harmonisation of the legal framework across the EU, **the CPME calls on the regulator to further facilitate the development of interoperable and secure systems of data processing and transfer between and within member states**. Furthermore, in cases of **cross-border transfer of information it is of utmost importance to ensure that patients have full information and legal certainty as to their rights and have given their explicit consent to the transfer and processing of their data**.

**CPME welcomes the proposals of the Commission aimed at enhancing the rights of the data subjects to access and amend their data**. According to official polls, physicians are considered the most trusted professional group by the European citizens when asked about trust and transmission and storage of personal data[1]. This demonstrates that not only the relationship trust-confidentiality between the patient and the physician works but also that the current framework of health data protection proves to be safe and secure.

In light of the above, **CPME is particularly concerned with the new provisions regarding the data subject's consent**. CPME agrees with the Commission to strengthen the subject's consent as regards secondary use of health data, such as clinical audits and research. **As regards the collecting and sharing of patient information in support of healthcare within a defined healthcare team, CPME believes that implied consent should be equally acceptable as written consent. Furthermore, the patient should have the right to 'opt out' from giving his/her consent regarding the own healthcare data.** The CPME is of the opinion that secondary use of health data for non-medical purposes should be limited to absolute necessary minimum and very precisely defined. Where it is only possible they should be anonymized in a way which prevents connecting them with patient's personal data.

Article 7 para. 4 specifies that ***"consent shall not provide a legal basis for the processing when there is a significant imbalance between the data subject and the controller".*** CPME understands that this provision is drafted to apply in the employer-employee relationship. However, this might also apply in the treatment context where the patient evokes a "significant imbalance" between the physician and himself in order to declare the consent given void.

The CPME would therefore recommend to amend Article 7(4) as suggested in the following pages.

[1] Eurobarometer 225, 2008 : '82% of interviewees have trust in medical services and doctors to keep personal info adequately protected

In line with the Commission's aim to enhance the rights of the data subjects, the proposed Regulation introduces the "right to be forgotten", a re-affirmation of the existing right under the current Directive to deletion of personal data after the purpose for which they were processed has been fulfilled. **While understanding the need of the "right to be forgotten" for the data subjects as to certain business models, CPME disagrees with the proposed scope for this concrete right**. The CPME strongly believes that healthcare data should be stored, with the appropriate security standards, in order to support future patient's safety and also allow proving the medical treatments and decisions made by any European physician, with the highest degree of legal certainty and accountability. CPME understands that the total erasure of data cannot always be ensured in its totality. Should the erasure be made, we call on the regulator to introduce a reasonable delay for the controller to respond to the erasure request[2]. In light of the above, **the CPME would call on the legislator to enlarge the proposed exceptions as regards the scope of the "right to be forgotten" to "healthcare data".[3]**

The CPME therefore advises to amend Recital 53 and Article 17.3(b) as suggested in the following pages.

As regards the enhancement of the data controllers' responsibility proposed by the Commission, the **CPME is concerned about the appointment of an independent "data protection officer" and the obligation of carrying out data protection impact assessments when health data is processed**. CPME is of the opinion that these new measures would result in a heavy administrative and economic burden for the small and medium health care entities. The CPME calls on the legislator to study carefully the administrative and economic costs that these new requirements would have in the small and medium health care entities before adopting any additional and compulsory measures.

The CPME would therefore recommend to ask the European Commission for clarifications on Articles 33 and 35 as suggested in the following pages. The CPME would also ask for clarifications whether Art. 34. Para. 2 (prior consultation) applies in a third country context only.

Finally, the CPME fully supports the Commission's proposal to adopt strict legal provisions in the form of economic and/or administrative sanctions applicable to those infringing the provisions of the Regulation.

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[2] Art 17.3 of the proposed Commission Regulation states that 'the controller shall carry out the erasure without delay'

[3] In the interest of legal certainty and while recognising the limits stipulated by law, it would be desirable to express more clearly that these exceptions (also in the light of the recitals (53) and (59); Article 17.3(d); Article 17.4(b) and Article 81) apply to health care data processed in a patient-doctor relationship.

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**Amendment 1**

**Recital 53**

| Proposal of the Commission | Amendment |
|---|---|
| (53) Any person should have the right to have personal data concerning them rectified and a 'right to be forgotten' where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for ***reasons of public interest in the area of public health***, for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. | (53) Any person should have the right to have personal data concerning them rectified and a 'right to be forgotten' where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for ***health purposes,*** for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. |

Justification

In the interest of legal certainty and while recognising the limits stipulated by law, the exceptions for the erasure of data by the controller (also in the light of the recital (59); Article 17.3.(b); Article 17.3(d); Article 17.4(b) and Article 81) should apply to health care data processed in a patient-doctor relationship.

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**Amendment 2**

**Article 7 - Conditions for consent**

| Proposal of the Commission | Amendment |
|---|---|
| 4. Consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller. | 4. Consent shall not provide a legal basis for the processing, where there is a ***coercive relationship*** between the position of the data subject and the controller. |

Justification

The provision of significant imbalance is drafted to apply in the employer-employee relationship. However, this might also apply in the treatment context where the patient evokes a "significant imbalance" between the physician and himself in order to declare the consent given void.

**Amendment 3**

**Article 17 – Right to be forgotten and to erasure**

| Proposal of the Commission | Amendment |
|---|---|
| 3. The controller shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary:<br>(a) for exercising the right of freedom of expression in accordance with Article 80;<br>(b) for reasons ***of public interest in the area of public health in accordance with Article 81;***<br>(c) for historical, statistical and scientific research purposes in accordance with Article 83;<br>(d) for compliance with a legal obligation to retain the personal data by Union or Member State law to which the controller is subject; Member State laws shall meet an objective of public interest, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued;<br>(e) in the cases referred to in paragraph 4. | 3. The controller shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary:<br>(a) for exercising the right of freedom of expression in accordance with Article 80;<br>(b) for reasons ***in accordance with Article 81;***<br>(c) for historical, statistical and scientific research purposes in accordance with Article 83;<br>(d) for compliance with a legal obligation to retain the personal data by Union or Member State law to which the controller is subject; Member State laws shall meet an objective of public interest, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued;<br>(e) in the cases referred to in paragraph 4. |

Justification

In the interest of legal certainty and while recognising the limits stipulated by law, the exceptions for the erasure of data by the controller (also in the light of the recitals (53) and (59); Article 17.3(d); Article 17.4(b) and Article 81) should apply to health care data processed in a patient-doctor relationship

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| Written question to the European Commission |
| Subject: Revision of the Data protection Directive |
| The European Commission published on 25 January 2012 its proposal for a comprehensive Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data.<br><br>The proposed Regulation is horizontal and covers very diverse areas and sectors for which data may be processed. This includes health data.<br><br>1. As regard the data protection impact assessment (Art. 33) and the data protection officer (Art. 35), how does the Commission foresee the economic burden for small and medium sized healthcare entities to comply with the requirements of Art. 33 and Art. 35?<br>How will the Commission approach this specific issue while adopting delegated acts?<br><br>2. Does Art. 34. Para. 2 (prior consultation) apply in a third country context only? |