COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

To: Health Attachés; Justice and Home affairs Attachés

Brussels, 3 December 2014

General Data Protection Regulation

Dear Health Attaché,
Dear Justice and Home Affairs Attaché,

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].

On 9 and 10 October, the Justice and Home Affairs (JHA) Council reached a partial general approach on specific aspects of the draft regulation setting out a general EU framework for data protection. In view of the next JHA Council meeting on 4 and 5 December, we would like to highlight the following points:

Preliminary remarks

- We favour the approach of the European Commission to revise Data Protection Directive 1995/46/EC and to introduce the highest level of protection for the treatment, processing, storage and transfer of personal data, especially of health and medical data.

- We stress that applicable principles of medical ethics should neither be weakened nor circumvented in the future European data protection legal framework. In particular, patients' autonomy and right to self-determination should be respected and protected.

Right to be forgotten and to erasure (Article 17)

1. In the treatment context, doctors access medical records on a daily basis. We believe medical records should be excluded from the right to be forgotten and to erasure. Such an exemption

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.
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is essential to ensure safe provision of care, the audit of such care as well as to comply with legal requirements such as when a complaint is filed.

Data protection impact assessments (Article 33) and data protection officers (Article 35)

2. In the treatment context, small and medium sized medical practices, where most European doctors practice, should be exempt from conducting data protection impact assessments and hiring data protection officers. The conduct of data protection impact assessments and the hiring of data protection officers would be significantly costly and potentially unsustainable for small medical practices which often function with limited staff resources and budgets. It is important that financial and administrative obligations are ruled in a way not to impede physicians to provide high quality care to their patients. In this regard, CPME favours the Commission's proposal which allows through delegated acts a well-balanced and proportionate solution that would take into account the specificities of small and medium sized enterprises.

Processing health data for archiving, statistical, scientific, and historical purposes (Article 83)

Advances in medical knowledge and innovation depend on high quality medical research. The development of medical research has huge societal benefits and is essential to maintaining and enhancing the health of a population. In this framework, ethical standards are key to ensure the good conduct of medical research with the highest level of protection of patients participating in research. Unfortunately, we believe the JHA Council text version 15544/14 (dated 14 November 2014) is too weak in ensuring the respect of ethical standards in the field of medical research:

3. Anonymisation, pseudonymisation and identifiable data: In medical research, as a principle and in order to ensure patients' right to privacy is respected, a three step approach is always required. The preferred option to access health data, should always be that the data is anonymised. As a second option, if anonymisation is not possible, the data should be pseudonymised. As a last resort, and only if the first two options are not implementable, can the data be kept identifiable. It is important to note that anonymisation and pseudonymisation techniques should be as efficient as possible in order to avoid having recourse to the last option of accessing identifiable data. This three step approach was correctly reflected in the Commission's proposal, thereby respecting the principles of data minimisation and purpose limitations. It is unfortunately lacking in the Council text, and we would strongly recommend it to be re-introduced.

4. Consent requirements: The approach taken by the Council on consent requirements in the field of medical research is highly unbalanced. Recital 125aa) indeed states that: *"(...) Consent from the data subject should not be necessary in each case."* As a principle, the use of data for medical research can only be done after an explicit consent from the data subject has been obtained. Only in exceptional cases, can derogations be introduced. For instance, if it is

proven impossible or impractical to go back to the patient to seek his/her consent, consent may not be required. However, this exemption has to be first approved by an independent ethics committee, or in the UK by the Confidentiality Advisory Group. These rules are set in stone in paragraph 32 of the WMA Declaration of Helsinki[2]. We therefore believe recital 125aa) should be formulated in a way that while exceptions may occur, consent should always stay the rule for the ethical conduct of medical research.

5. Governance structures: Article 83 as amended by the Council, foresees possible derogations from the provisions outlined provided that Member States ensure *"appropriate safeguards for the rights and freedoms of the data subject"*. The reference to the implementation of safeguards at Member States level is insufficient. Indeed, we believe the Council text should explicitly refer to governance structures already in place at national levels, such as independent research ethics committees and other independent review boards entitled to oversee such processes, or in the UK by the Confidentiality Advisory Group. An explicit reference to such governance structures is of particular importance in the cases where identifiable data is needed for medical research purposes while at the same time the data subject's explicit consent cannot be sought.

6. Biobanks and other health databases: In the last decades the development of health databases and biobanks has grown extremely rapidly, and the potential of information they contain for medical research is enormous. These technical developments should not set aside ethical principles. Individuals should have the right to decide whether they want their identifiable data to be included in these databases. To this aim, individuals need to be aware of what their data will be used for, who will access them, the nature of the data and material that will potentially be accessed. Individuals also need to know what is the governance structure in place and the measures taken to protect their privacy. Considering the pace at which these technical developments advance, we believe it is all the more important to ensure that strong safeguards, protection mechanisms and governance structures are in place. While we recognise this is a Member States' competence, we still believe the General Data Protection Regulation should provide with a general framework recognising key ethical principles. It is essential that the legal framework for health data protection strikes a balance between enabling valuable medical research to progress whilst maintaining existing standards of confidentiality and public trust in health services and professionals.

We believe these recommendations are crucial to ensure the new legislation genuinely benefits the provision of high quality healthcare and that patients' autonomy and right to self-determination are respected and protected.

[2] http://www.wma.net/en/30publications/10policies/b3/index.html

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Sincerely,

[redacted] - [redacted]

[redacted]
CPME President

[redacted]
CPME Secretary General