The Reform of European Data Protection Law

- Why does it matter to the discussion? -

RA Annabel Seebohm, LL.M.
Legal Advisor, World Medical Association

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Outline

- European Commission Proposal
- Stakeholder
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- Council
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European Commission Proposal

Objectives

- Harmonize the current patchy data protection laws in Member States by a single European regulation
- Adapt data protection law to the needs of the 21st century
- Privacy by design

European Commission Proposal

Process

- European Commission proposal January 2012
- European Parliament amendments March 2014
- Council amendments June 2015
- Trilogue negotiations June - December 2015

European Commission Proposal

Aspects

- **Principles:** Data minimisation and purpose limitation
- **Consent:** Processing of personal data is lawful only if based on consent, contract, compliance with a legal obligation or a claim.
- **Safeguards:** Processing of sensitive data including data concerning health is prohibited unless:

- explicit consent is given or
- sector specific exemptions apply allowing processing which is necessary e. g. for healthcare and research without explicit consent provided national laws and specific safeguards/guarantees are in place.

Stakeholder

Joint Statement of the Healthcare Coalition on Data Protection

Benefits of data processing in healthcare and medical sciences while protecting patients' personal data

Representing leading actors of the healthcare sector in Europe, the Healthcare Coalition for Data Protection[1] would like to share their thoughts on the Commission's proposal for a General Data Protection Regulation. [2]

The Healthcare Coalition for Data Protection welcomes the Commission's effort to harmonise data protection requirements in the EU. The Coalition also welcomes the provisions supporting healthcare and health research. However, some areas must be improved to facilitate medical innovation, improvements in care delivery, and to support Europe's ground-breaking medical research for the benefits of society. Certain provisions might restrict the sharing of health data, delay innovation, create legal uncertainty and increase compliance costs if they remain unchanged.

WMA

Stakeholder

CPME

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)

WMA

Stakeholder

Avenue E. Mounier 83/11
1200 Brussels
Belgium
Tel: +32 2 774 1611
Email: eortc@eortc.be
www.eortc.org

EORTC strongly suggest EU creates the legal framework that will foster transparent, ethical and patient centered health research by:

- **specifically recognizing the importance of health research as the only mean to ensure adequate healthcare**
- **facilitating international health research, specifically within EU**
- **recognizing the difference between fully identified and pseudo-anonymized data and confirming the use of pseudo-anonymized data as a valid mean to protect privacy with associated lightened framework**
- **supporting the principle of "one time consent"**
- **allowing prolongations of storage and secondary use of data initially collected for a different research project and/or purpose**
- **allowing exemptions from consent for registries and for situations where consent is impossible or impracticable to obtain based on Helsinki declaration.**

Stakeholder

Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community

On 12 March 2014, the European Parliament voted on its position on the new European Union (EU) proposal for a General Data Protection Regulation, which will be now negotiated among the European Parliament, the Council of the European Union and the European Commission [1]. The final text will set the rules under which personal data are to be handled in the EU. It will thus affect many areas of our everyday life, including health and research. The cancer community is deeply concerned about unintended consequences of the current wording of the draft Regulation [2], which may put at stake the survival of retrospective clinical research, biobanking, and population-based cancer registries in the EU. In fact, the EU Parliament's recent. Resolution [3] on the Regulation imposes, or may be interpreted as imposing, the requirement for researchers to ask for a patient's 'specific' consent every single time new research is carried out on already available data and/or tissues. This would lead to the necessity of researchers continuously asking patients to 're-consent' for every single use of their data. In fact, the European Parliament's Resolution [3], Amendment 191 states that,

1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of

This text now forms the official position of the European Parliament. On behalf of the European oncology community, the entities endorsing this position paper would like the ongoing legislative negotiation process on the draft text to find the right balance to fully protect the privacy of patient data,

endorsements

This ESMO position paper on the EU General Data Protection Regulation is endorsed by the following organisations, and under review for endorsement by additional organisations:

European Organization for Research and Treatment of Cancer

European, Middle Eastern & African Society for Biopreservation and Biobanking

Eurocan Platform

European Society of Surgical Oncology

European Society of Pediatric Oncology

Stakeholder

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

16 June 2015 Day of Action 'Data for Health and Science'

3. **Harmonised rules for research at EU level would be preferable** to promote trans-national research collaboration. At the same time, the harmonised rules should not lead to a deterioration of the status quo for research. In particular, harmonised rules would be extremely valuable for rare diseases, as Pan-European studies are often necessary to obtain sufficient data, given the small numbers of patients affected across a single country.

4. **The exemption from consent and other exemptions** provided for historical, scientific, and statistical research in the Commission's proposed General Data Protection Regulation and in the Council's general approach **should be maintained** to avoid negative effects on research, including biomedical research, which is a highly controlled area with many safeguards in place to protect the confidentiality of any information about patients.

WMA

Stakeholder

Protecting health and scientific research in the Data Protection Regulation (2012/0011(COD))
Position of non-commercial research organisations and academics – May 2015

Health and scientific research will be severely threatened if the amendments to Articles 81 and 83 of the Data Protection Regulation adopted by the European Parliament are taken forward. Scientific research generates important benefits by improving our understanding of society, health and disease. If implemented, the amendments would make much research involving personal data at worst illegal, and at best unworkable.

In order to protect valuable research while protecting privacy, we urge:

- **the Council of Ministers to maintain the Commission's text on Articles 81 and 83 and associated provisions when agreeing its general approach;**
- **MEPs to seek a more positive outcome for research in trilogue negotiations; and**
- **the Council of Ministers and European Commission to oppose the European Parliament's amendments to Articles 81 and 83 in trilogue negotiations.**

Position of non-commercial research organisations and academics on the Data Protection Regulation – May 2015

Position of non-commercial research organisations and academics on the Data Protection Regulation – May 2015

European Parliament

Amendment 3057
Claude Moraes, Glenis Willmott

Proposal for a regulation
Article 83 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) where data are to be processed for scientific research purposes, the proposed scientific research project has received a favourable opinion from an independent research ethics committee

Or. en

Justification

This reflects the role of ethics committees which are an important safeguard that underpins the use of personal data in research without specific consent. Combined with the amendment to Recital 124, this amendment would make the article consistent with the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2008)

European Parliament

Amendment 3059
Nils Torvalds

Proposal for a regulation
Article 83 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) in case data is to be processed for scientific research purposes, the proposed scientific research project has received a favourable opinion from an independent research ethics committee

European Parliament

Amendment 3068
Anna Hedh, Marita Ulvskog

Proposal for a regulation
Article 83 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Further processing of sensitive personal data for medical research purposes may be allowed in line with relevant national and EU legislation and after a favourable opinion by an Ethics Committee.

Or. en

Justification

The re-use personal data is if great importance when new research questions arise that could not be foreseen when the data was collected. The condition for re-use should be laid down in national legislation and include investigation and approval of Ethics Committee.

European Parliament

Amendment 3066
Sari Essayah

Proposal for a regulation
Article 83 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. A person may give consent that sensitive data concerning that person may be used for non-specified historical, statistical or scientific research purposes without the person receiving information about each specific research project.

European Parliament

Amendment 3067
Nils Torvalds, Eija-Riitta Korhola, Riikka Manner

Proposal for a regulation
Article 83 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The data subject has given his or her consent for the processing of data for historical, statistical and scientific research. For the purposes of historical, statistical and scientific research, a one time consent is enough and there is no need for explicit consent to be given each time by the data subject, or a need to notify the data subject, separately before the processing of data related to research purposes.

European Parliament

Amendment 3079
Sarah Ludford, Charles Tannock

Proposal for a regulation
Article 83 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where the data subject is required to give his/her consent under this article, the option of broad consent should be available.

Or. en

Justification

'Broad consent' is a practical solution in the context of research.

European Parliament Final

Article 81

Processing of personal data concerning health

In accordance with the rules set out in this Regulation, in particular with point (h) of Article 9(2), processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable, consistent, and specific measures to safeguard the data subject's interests and fundamental rights, to the extent that these are necessary and proportionate […]

1a. When the purposes referred to in points (a) to (c) of paragraph 1 can be achieved without the use of personal data, such data shall not be used for those purposes, unless based on the consent of the data subject or Member State law.

1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.

1c. For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC shall apply.

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes shall be permitted only with the consent of the data subject, and shall be subject to the conditions and safeguards referred to in Article 83.

2a. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data […]

Council

Article 83
Derogations applying to processing of personal data for archiving purposes in the public interest or for scientific, statistical and historical purposes

[…]

2. The appropriate safeguards referred to in paragraphs 1 and 1a shall be laid down in Union or Member State law and be such to ensure that technological and/or organisational protection measures pursuant to this Regulation are applied to the personal data […], to minimise the processing of personal data in pursuance of the proportionality and necessity principles, such as pseudonymising the data, unless those measures prevent achieving the purpose of the processing and such purpose cannot be otherwise fulfilled within reasonable means.

Council

Article 5
Principles relating to personal data processing

1. Personal data must be:

(a) processed lawfully, fairly and in a transparent manner in relation to the data subject;

(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; further processing of personal data for archiving purposes in the public interest or scientific, statistical or historical purposes shall in accordance with Article 83 not be considered incompatible with the initial purposes;

Conclusions

- Notwithstanding lingering questions as to the principle of purpose limitation (and the reuse of data plus consent needed), the Commission and Council approaches reaffirm the status quo in scientific research in that it‘s „Member States business“.
- A harmonised European approach towards scientific research including the use of health data bases and biobanks appears desirable.
- To achieve a harmonised European approach by law - as of today - appears unrealistic. Also, data protection law may not be the right place to resolve ethical questions pending in medical research.

Outlook

- Are codes of conduct a possible alternative?

Article 38
Codes of conduct
[…]
1a. Associations and other bodies representing categories of controllers or processors may prepare codes of conduct, or amend or extend such codes, for the purpose of specifying the application of provisions of this Regulation, such as:

(a) fair and transparent data processing;

(aa) the legitimate interests pursued by controllers in specific contexts;