



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 Protection¹ 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.

The Healthcare Coalition on Data Protection proposes five key recommendations to improve the General Data Protection Regulation:

1. Maintain provisions for data processing for healthcare, research and ultimately patient safety.
2. Clarify definitions for data concerning health to allow a workable and effective data protection regime.
3. Consider the potential unwanted consequences of the Right to be Forgotten.
4. Avoid excessive administrative burden linked to impact assessment obligations.
5. Clarify rules and definitions around the concept of consent.

¹ See last page for more explanation on the Healthcare Coalition on Data Protection

² http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

DETAILED BRIEFING

1. Maintain provisions for data processing for healthcare, research and ultimately patient safety

Today's modern information-based healthcare systems rely on data processing to deliver quality care. The availability of health data through the healthcare cycle is crucial for delivering quality care, clinical research, public health research, improving the quality of patient-centred healthcare services and reducing costs. ICT, electronic health records and mobile technologies are increasingly connecting all parts of the system delivering more personalised 'citizen-centric' healthcare, which is more targeted, effective and efficient.³ Underpinning this emerging ecosystem is data. Not only is data crucial to responding to patient needs, but it also helps in defining public health policy development.

To capitalise on these benefits, it is vital that the EU strikes an appropriate balance between facilitating the secure use of health data for health purposes and patients' rights to privacy.

The Coalition recommends the provisions of article 81 and 83 are maintained and clarified as the Regulation moves through the legislative process.

2. Clarify definitions for data concerning health to allow a workable and effective data protection regime

Anonymised, and pseudonymised or key-coded data are used to conduct medical research, monitor the efficiency of treatments, monitor disease trends, support public health policies, etc.

The Coalition recommends:

- Amending Article 2 (material scope of the Regulation), to make explicit that the principles of data protection should not apply to data rendered anonymous (as recognised in Recital 23)
- Introducing a definition of anonymised data in Article 4(2) (b) and pseudonymised data in Article 4(2) (a).
- Adopting a proportionate approach to the use of pseudonymised data that recognises the context and the risk of re-identification to ensure a risk-based approach, as reflected in the opinion 4/2007 of the Article 29 Working Party Opinion⁴. In addition, the Regulation should create incentives for using pseudonymised data, by relieving certain restrictions.
- To ensure legal clarity, the regulation must ensure consistency with other EU legislation. For instance certain types of data (e.g. location data, online identifiers as defined in article 4(1), are already covered by the e-privacy Directive 2002/58EC, creating confusion.

3. Consider the potential unwanted consequences of the Right to be Forgotten

³ eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century, COM (2012) 736 final

⁴ http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp136_en.pdf

Implementing the right to be forgotten and to erasure in the healthcare context requires careful consideration of the consequences:

- Deleting data from electronic health records may run counter to individual treatments and patient safety: healthcare providers will not have access to life-saving information on the patient when establishing a diagnosis, such as allergies, ongoing treatments, specific conditions (e.g. diabetes), blood type, medical history, organ donation, etc.
- Statistical analyses might be weakened, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.

We are concerned that whilst Article 17(3)(b) provides an exemption '*for reasons of public interest in the area of public health*', it is not clear whether this exemption applies to healthcare provision.

The Coalition recommends that Article 17(3) (b) is clarified in order to exclude the possibility of erasing data concerning health.

4. Avoid excessive administrative burden linked to impact assessments obligations

A key objective of the reform is to make data controllers accountable for their processing of personal data, while avoiding excessive administrative burden. However a few provisions risk creating legal uncertainty and bureaucratic complexity:

- Article 33 requires that the processing of data concerning health is subject to the data protection impact assessment requirement, but the criteria for impact assessments are not defined and may be clarified by delegated act (Article 33 (6)).
- In addition, while Article 34 prohibits certain processing of personal data before approval by the supervisory authority, it does not specify the timelines for the approval process. Legal certainty concerning the approval process of supervisory authorities is crucial for stakeholders.

The Coalition recommends:

- Article 34 should mirror the principles outlined in recital 74: mandatory prior consultation should only be foreseen for:
 - Very limited processing activities, which could be privacy invasive and which differ significantly from existing processing activities
 - Risky processings which might obviously not be in compliance with the Regulation.
- Article 34 should set out a clear timeline for the approval of supervisory authorities
- A single data protection assessment should be permitted to cover similar processing activities and activities which present similar privacy risks.
- Impact assessments should not be "one-size-fits-all". Under a principle of accountability, organisations should be able to adopt impact assessments, appropriate to their type of organisation and processing activities, legal requirements and contractual obligations. The delegated and implementing acts (Article 34 (8-9)) should be deleted.

- Impact assessments should not constitute disproportionate and unsustainable administrative and financial burden to small and medium sized medical practices.

5. Clarify rules and definitions around the concept of consent

The Coalition warmly welcomes high visibility of consent in the draft Regulation, and endorses the philosophy that consent is the basis of trust. However the lack of clarity on the way in which consent is to be treated in the context of healthcare and research is a matter of some concern. In healthcare, data protection should strive for an appropriate balance between a data subject's rights, and innovative use of information to support research and greater patient empowerment for self management.

We believe current proposals for consent may lead to a burdensome notice and 'opt-in' regime for individuals, overwhelming patients with information and creating significant resource demand.

The Coalition recommends:

- In the context of healthcare provision it is noted that Article 7(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*". The current wording might result, in the patient invoking a "significant imbalance" between the physician and himself in order to declare the consent given void. Whilst it is understood that in certain cases, such as employment, it is important to have such safeguards, the Regulation should explicitly clarify that art. 7(4) does not apply to the health sector.
- A doctor cannot provide treatment without processing patients' personal data. The Regulation should clarify that the act of seeking and agreeing to treatment should be considered as equal to 'explicit consent' in these contexts, and as per Article 4(8) and Article 7(1). This clarification would also avoid red tape.
- In the case of medical research, it should be noted that specific consent is not compatible with the approach taken in many research studies, where a broad consent model is used. There are also cases where it is difficult or impossible to secure consent. Article 83 provides an alternative legal basis for processing for research under which consent for processing of appropriately-protected data will not be required. It is therefore particularly important that Article 83 and the associated rules are clear and maintained in all delegated legislation.

The Healthcare Coalition on Data Protection gathers:

CED:

The [Council of European Dentists](#) (CED) is the representative organisation of the dental profession in the European Union, representing over 340,000 practicing dentists from 32 national dental associations and dental chambers in 30 European countries. Established in 1961, the CED promotes high standards of oral healthcare and effective patient-safety centered professional practice across Europe and contributes to the safeguarding and the protection of public health.

HOPE:

[HOPE](#), the European Hospital and Healthcare Federation, is an international non-profit organisation, created in 1966. HOPE represents national public and private hospital associations and hospital owners, either federations of local and regional authorities or national health services. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

FEAM:

The [Federation of European Academies of Medicine](#) (FEAM) represents national academies in 14 EU member states. Its mission is to promote cooperation between the national Academies of Medicine and to extend to the political and administrative authorities of the European Union the advisory role that the Academies exercise in their own countries on matters concerning medicine and public health.

COCIR:

[COCIR](#) represents the Radiological, Electromedical and Healthcare IT industry in Europe. COCIR encourages the use of advanced technology to support healthcare delivery worldwide and promotes free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

EFPIA:

The [European Federation of Pharmaceutical Industries and Associations](#) (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 37 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world. EFPIA supports a vision of modern and sustainable healthcare systems in Europe, where patients have equal and early access to the best and safest medicines, which supports innovation, empowers citizens to make informed decisions about their health and ensures the highest security of the medicines supply chain.

Continua Health Alliance:

[Continua Health Alliance](#) is a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. With more than 220 member companies around the world, Continua is dedicated to establishing a system of interoperable personal connected health solutions.

GSMA:

The GSMA represents the interests of mobile operators worldwide. Spanning more than 220 countries, the GSMA unites nearly 800 of the world's mobile operators with more than 230 companies in the broader mobile ecosystem, including handset makers, software companies, equipment providers and Internet companies, as well as organisations in industry sectors such as financial services, healthcare, media, transport

and utilities. The GSMA also produces industry-leading events such as the Mobile World Congress and Mobile Asia Expo.

mHealth is one of the focus areas of the GSMA's Connected Living programme, a market development initiative that is designed to help operators accelerate the delivery of new mobile connected devices and services. The purpose of the GSMA's mHealth initiative is to support cost-effective delivery of better healthcare for everyone.

For more information, please visit the GSMA corporate website at www.gsma.com or Mobile World Live, the online portal for the mobile communications industry, at www.mobileworldlive.com.

CPME:

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.

We believe the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice, the safe mobility of physicians and patients, lawful and supportive working conditions for physicians and the provision of evidence-based, ethical and equitable healthcare services. We offer support to those working towards these objectives whenever needed.

We see the patient-doctor relationship as fundamental in achieving these objectives and are committed to ensuring its trust and confidentiality are protected while the relationship evolves with healthcare systems. Patient safety and quality of care are central to our policies.

We strongly advocate a 'health in all policies' approach to encourage cross-sectorial awareness for and action on the determinants of health, to prevent disease and promote good health across society.

CPME's policies are shaped through the expertise provided by our membership of national medical associations, representing physicians across all medical specialties all over Europe and creating a dialogue between the national and European dimensions of health and healthcare.