Healthcare Coalition on Data Protection

4 key recommendations to facilitate healthcare and health research for the benefit of patients

Representing leading actors in the healthcare sector in Europe, the Healthcare Coalition on Data Protection would like to put forward recommendations designed to clarify and improve provisions related to health as included in the European Commission's proposal for a General Data Protection Regulation[1], in the European Parliament's amendments[2] and the Council's Partial General Approaches on this Regulation.

The Healthcare Coalition on Data Protection proposes four key recommendations on the General Data Protection Regulation to facilitate healthcare and health research for the benefit of patients:

1. **Clarify the conditions under which personal health data may be used for research and healthcare purposes**

2. **Clarify how privacy rights are to be applied in the context of research and healthcare purposes**

3. **Avoid excessive administrative burden**

4. **Provide more flexible procedures and mechanisms for exercising the rights of the data subject**

[1] *http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf*
[2] *http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0402+0+DOC+XML+V0//EN&language=en*

DETAILED BRIEFING

1. Clarify the conditions under which personal health data may be used for research and healthcare purposes

- The Parliament's report adopted in March 2014 has provided both a requirement for 'specific' consent for the use of data concerning health in scientific research and an exception to this requirement in the case of pseudonymised data. It has also introduced a public interest test for research. Pseudonymisation, detailed consent procedures and oversight of re-use of data are well-established practice in health research. A requirement for 'specific' consent will make it very difficult or impossible for some research studies to process personal data concerning health especially with regard to future health research. At the time of data collection, e.g. when creating a register of disease survival rates or collecting information from patients on treatment outcomes, it is not possible to describe all potential uses in detail.

→ The provisions in the Commission's text to facilitate the processing of appropriately protected personal data and for such data to be held for extended periods for research purposes should be maintained.
→ The Coalition welcomes the approach taken by the Council on articles 5, 6 and 9 of its Partial General Approach on Chapter II, which has clarified the basis on which data including pseudonymised / key-coded data may be used for healthcare and research purposes.

- Research using data concerning health is conducted within a rigorous regulatory and governance framework, enshrined in national and international laws, and researchers follow guidance built on strong ethical principles.

→ The Council's Partial General Approaches on Chapters II and IX recognise the importance of proportionate and appropriate safeguards and this approach should be maintained in the final text.

- The Coalition recognises that the Council is committed to the national arrangements under which healthcare and research are currently regulated. However a purely national approach may undermine goals in the area of European research collaboration and will not address the administrative burden encountered by researchers attempting to carry out cross-border research.

→ The Regulation must provide the possibility to introduce implementation measures applicable across the EU where these would facilitate European research and competitiveness policy objectives.

2. Clarify how privacy rights are to be applied in the context of research and healthcare purposes

- Implementing the right to be forgotten and to erasure and the right to rectification in the healthcare and research context requires careful consideration of the consequences:
  - Deleting data from electronic health records may run counter to patient diagnosis, treatment and safety. For example, lacking access to previous data (whether referring to diagnosis, treatments, biology, imaging, etc) can lead to erroneous decisions (either by excess or by default) as for investigations and treatments, with possible life-threatening consequences.
  - Statistical analyses might be weakened, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.
  - In the same way with regards to rectification, it is important in a healthcare context that medical hypothesis and speculation can be retained within an individual's health record as this may prove crucial to the appropriate delivery of healthcare to the data subject at a later date.

→ While Article 17(3)(b) from the Commission's text and the Parliament's adopted position 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. A clarification would be needed on the fact that the exemption includes healthcare purposes. A similar exemption for healthcare purposes should also be included in Article 16.

- The application of other privacy rights such as access and information will require careful consideration in relation to personal data which has been pseudonymised for research purposes.

→ The Coalition supports Article 10 of the Commission's proposal which clarifies that rights are exercisable in relation to directly-identifiable data.

3. Avoid excessive administrative burden

- The definition of a data subject proposed by the European Commission and the European Parliament is deliberately broad and includes data that may help to identify or single out a data subject, directly or indirectly. This could lead to unintended consequences. For instance the serial number used to identify a medical device (e.g. a CPAP, heart-rate monitor,, etc.) may be regarded as personal data subject to the Regulation, as may location. This may increase the

administrative burden for medical device manufacturers, by requiring additional individual consent/authorization to process these data elements (for inventory control, periodic maintenance, end-of life/replacement purposes, etc.), without bringing any additional privacy protections to the individual patient. It is also crucial to ensure that the definition of data subject maintains the wording 'by means reasonably likely to be use'. The European Parliament has proposed deleting this phrase from the definition. We think this text is extremely important as it recognises the necessity to take into account the context when defining whether data are at risk of being identifiable. This wording ensures that anonymisation does not have to be completely risk free. It is clear that the risk of identification must be remote (particularly for the special categories of data), but 100% anonymisation is not the legal test.

→ Article 4 should take a proportionate and context-specific approach to the definition of personal data, by taking into account the 'means reasonably likely to be used' to identify an individual.

- Also, the Commission proposal and the Parliament's amendments provide prescriptive obligations for carrying out impact assessments. Healthcare organisations should be able to maintain their own assessment, based on their specific type of organisation, legal requirements, contractual obligations, and, where appropriate, internal policies, provided this assessment safeguards the interests of individuals. Where organisation carry out similar processing operations on different data sets, a single impact assessment should be sufficient, unless the risks are materially different.

→ Unnecessary administrative burden linked to impact assessment obligations should be avoided.

4. Provide more flexible procedures and mechanisms for exercising the rights of the data subject

- It will be challenging for healthcare organisations to meet the timeline stipulated in article 12 to respond to access requests. Not only do healthcare organisations receive a large number of requests but a significant proportion of health records are not yet available electronically. Healthcare organisations are working to input all data retrospectively but this is a huge undertaking as it requires inputting data for the entire duration of the individual health record of every single data subject within their system as well as from across other systems. The healthcare environment has a multi-contributory records environment. There is also a need to ensure that any data passed on to the data subject does not inadvertently betray the privacy of third parties who may be mentioned within the record. For

this reason, the record may have to be adapted before it is shared with the data subject. More time is required to do this.

→ The Regulation should allow for more flexible timelines to respond to requests, if the nature of the data requested requires them to be reviewed before they are made available to the data subject.

- Furthermore, article 12 paragraph 4 states that information provided to the data subject should be free of charge, "unless where requests are manifestly excessive, in particular because of their repetitive character". While many hospitals are moving to electronic records, in most cases, a significant part of a data subject's health record remains mostly paper-based, and rather voluminous. It is time consuming and costly to go through the archives to find a complete record and for this reason many hospitals still charge a fee, in order to cover costs. If that information had to be provided free of charge, it will take funds from other services in order to cover costs.

→ The Regulation should be amended to specify that, in addition to where requests are manifestly excessive, in particular because of their repetitive character, also where requests are made for copies of data from a complex paper record held as part of a task carried out as a legal/public duty, such as a health record, the controller may charge a fee for providing the information.

ANNEX 1

What examples of type of practices would be ruled out by disproportionate data protection rules?

Article 81 – Processing of personal data concerning health
Article 83 – Processing for historical, statistical and scientific research purposes

- **German cancer registries** suffered when a requirement for consent was introduced in the 1980s. Under the new rules, these regions were unable to collect more than 70% of cancer cases. The Hamburg registry, which had collected cancer data for over 50 years, broke down and was no longer able to add its results to international cancer indexes. These difficulties led to new guidance from the Federal Government in 1994, which relaxed the requirement for consent in all regions. A similar phenomenon could be seen on a European scale if the Parliament's amendments to Article 81 are adopted in the final text.

- **The European Prospective Investigation into Cancer and Nutrition** (EPIC) is the largest study of diet and health ever undertaken and includes over half a million people in ten European countries. The data collected from participants is being used to understand the relationships between diet, nutritional status, lifestyle and environmental factors and the incidence of cancer and other chronic diseases. Health measurements, dietary and lifestyle surveys and samples have been collected from the same cohort of individuals since the 1990s. National cancer and death registries are used to follow up outcomes in participants. Collected data are used in pseudonymised form for a variety of studies consistent with the aims of EPIC. Participants gave broad consent for the use of their data and samples. This means that researchers seeking to use EPIC data would have to rely on the narrow consent exemption, but it is unclear whether it would fulfil the conditions to qualify for the exemption.

- **European Medical Information Framework** (EMIF) is a €56 million collaboration to link together existing health data from 40 million European citizens across seven EU countries. EMIF will make health data from a range of sources - including hospital databases, cohorts and national registries - accessible to researchers for studies on obesity and Alzheimer's disease. The development and use of this powerful research resource would be seriously threatened if the European Parliament's amendments are kept because the exemption from specific consent is very narrow.

- **Medical image processing software** needs to be proven safe and effective before it can be placed on the market. The development and testing of such software requires actual patient data. Today hospitals can de-identify, or strip their medical images from all identifiers (e.g. patient name, address, social

security number, etc.) before providing the images to manufacturers for development and testing purposes. Most national privacy laws consider that a medical image stripped from identifiable data is anonymous; therefore no patient consent is needed to use the image for research, development and testing purposes. However six European countries believe that it is not anonymised because the clinician can recognise the image and link it to his patient. As such, according to the law of those six countries medical images can never be called 'anonymous' and therefore always require patient consent. This implies a significant cost for manufacturers. Industry estimates a 25% cost increase:

- The cost of collecting the patient consent is estimated at 100€ per image.
- A new software algorithm may require thousands of images to develop and test.
- Minor software updates are tested on about a hundred images. Often there are several releases per year of a particular application.

Introducing a consent requirement will increase the development cost of medical image processing softwares, and slow it down, with no benefit to privacy.

Article 12 – Procedures and mechanisms for exercising the rights of the data subject

- Currently **Department of Health guidance issued to the NHS** (United Kingdom) allows charges to be made – a maximum charge of £10 for electronic records, and a maximum of £50 for records held in another format has been imposed. Guidance is very clear that no profit should be made from the activity. In the case of a service like the NHS, the customer/patient always has to pay for this service either directly or indirectly. A medium sized district Trust can receive approximately 50 requests every week. It is time consuming and costly to go through the archives to find a complete record and for this reason many Trusts still charge the maximum £50 charge, in order to cover costs. If that information had to be provided free of charge as stated in article 12, it will take funds from other services in order to cover costs. As an example, when a medium sized NHS Board in Scotland conducted an audit of access to health records requests a few years ago, they calculated the real cost to the NHS Board was approximately £400,000 per year[3]. While there is a strategic decision to aim for a paperless NHS, and for medical records held electronically to be provided to a patient free of charge, it would be appreciated if NHS organisations can maintain the flexibility to continue to charge, particularly for paper records, in order to reduce the cost and redirection of funds from other core services.

[3] These costs take into account, finding the records, a middle grade health records person going through the record to ensure that the request is fully complied with and the time lost to the NHS, whilst the individual is undertaking this activity, any redaction and the administrative costs such as photocopying and sending the records by either courier or recorded delivery.

ANNEX 2

Members of the Healthcare Coalition on Data Protection

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's (FEAM) mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide them with a platform to formulate and express their common position on European matters concerning human and animal medicine, biomedical research, education, and health; and to extend to the European authorities the advisory role that they exercise in their own countries on those matters. Our vision: (1) to underpin European biomedical policy with the best scientific advice drawn from across Europe, through the FEAM network of Academies representing over 5000 high level scientists from the whole biomedical spectrum, and (2) to improve the health, safety and wealth of European citizens through research by promoting a nurturing, creative and sustainable environment for medical research and training in Europe. FEAM's strength lies in its member Academies that give it the authority to provide an EU-wide scientific opinion on the European medical science base and evidence to underpin European biomedical policy. The FEAM Academies represent the following EU Member States: Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Netherlands, Portugal, Romania, Spain, United Kingdom.

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.

MedTech Europe:
Medtech Europe is an alliance of European medical technology industry associations. The Alliance was founded by EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical devices industry. Other European medical technology associations are welcome to join the Alliance, established to represent the common policy interests of its members more effectively and efficiently.
Our mission is to make value-based, innovative medical technology available to more people, while supporting the transformation of healthcare systems onto a sustainable path. We promote a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of its stakeholders. In addition, we demonstrate the value of medical technology by encouraging our members to execute the industry's 5-year strategy.

European Society of Radiology:
The European Society of Radiology (ESR, www.myesr.org) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of radiology in all European countries. The Society's mission at all times is to serve the healthcare needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology. The ESR is the European body representing the radiology profession with more than 62,000 individual members as well as all national radiological societies and subspecialty societies in Europe.
The ESR is an observer of the Healthcare Coalition on Data Protection.