



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proposal for a new legal framework for data protection in EU

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Background/1

- In EU, legislation on data protection is in place since **1995** (Directive 95/46/EC)- national implementation
- New **technological challenges** (Internet/cloud computing, video-surveillance, genetic data)
- **Institutional** changes (Art. 16 TFEU and Art. 8 Charter of Fundamental Rights)
- **Fragmentation and legal uncertainty** (3 billions euro dead weight loss for business) – inconsistent enforcement



Background/2

- Public consultation on the Comprehensive Approach on data protection January 2011; 168 responses, ENCePP contributed with a paper underlining the importance of the secondary use of health data
- 25th January 2012: EC proposes the reform: 1 Regulation (General Data Protection) 1 Directive (police and judicial cooperation) and a Communication:
http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm



Policy objectives

- Enhance the **internal market dimension** of data protection by reducing fragmentation, strengthening consistency and simplifying the regulatory environment
- **Empower individuals** in the control of their data (above all in the online environment); focus on building trust
- Streamline the structure for **obligations and responsibility** with regard to the processing of data



Key elements of the Regulation

- A new legal instrument –Regulation -that is **binding in its entirety and directly applicable** in all Member States
- DP Regulation maintain the **same objectives** (to protect personal data and to guarantee free flow of personal data)
- Better **information to individuals** and consent to be given **explicitly**
- **Right to be forgotten** and data “portability”
- Reinforce data security obligations on controllers



Key elements of the Regulation

- A more efficient regulatory system:
 1. “**one stop one shop**” concept for business; one DPA checks compliance of a business regardless of MSs
 2. abolishing notifications
 3. Increase **cooperation between DPAs**: mutual recognition of decisions; Article 29 WP becomes an independent *European Data Protection Board*
 4. Better **enforcement** and **enhanced judicial and administrative decisions**



The new proposal and health data

- The overarching scope is to bring **clarity**:

Recital 26; Recital 125-126.

Article 4 (Definition) (12) *data concerning health means any information which relates to the physical or mental health of an individual; or to the provision of health services to the individual*

Article 9 lawfulness of processing of data concerning health, including (a) consent under Article 7 and **(h) is necessary for health purposes** under Article 81 and **(i) is necessary for historical, statistical and research purposes** under Article 83



The new proposal and health data

- **Article 81** processing of data **without consent** for **health purposes**:
 - (a) Necessary for preventive or occupational medicine, medical diagnosis, the provision of care or treatment, the management of health-care services where data are processed by health-care professional subject to confidentiality
 - (b) Reasons of public interest in the area of public health, such as **protecting against serious cross-border threats** to health or ensuring **high standards of quality and safety, inter alia for medicinal products and medical devices**



The new proposal and health data

- **Art. 81 (2)**: Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as **patient registries** set up for **improving diagnoses and differentiating between similar types of diseases** and **preparing studies for therapies**, is subject to the conditions and safeguards referred to in **Article 83**.



The new proposal and health data

- **Art. 83** processing for **historical, statistical and research purposes, only if**
 - (a) these purposes cannot be fulfilled by data which do not permit or not any longer permit the identification of the data subject**
 - (b) Data enabling the attribution of an information to an identified or identifiable data subject is kept separately from the other information**



The new proposal and health data

- **Bodies** conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:
 - (a) The data subject has given **consent**,
 - (b) The publication of personal data is **necessary to present research findings** or **to facilitate research** insofar as fundamental rights do not override, **or**
 - (c) **The data subject has made the data public**



The new proposal and health data

In both Article 81 and 83, the EC can adopt **delegated acts** for further **specifying the criteria** and **requirements**...as well as any limitations for right of information and access to data

The question will be on drawing a line for establishing the **compatibility of purposes** of processing of personal data when a data subject has provided **consent**



Thank you!

For questions/discussion :

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