



**Disclaimer:** On 1 March 2013, EURORDIS elaborated and disseminated a “Statement on the European Parliament report on the Protection of Personal Data” in the context of the revision of the current EU Directive toward an EU [Regulation](#). This statement has been supported by a vast number of organisations/institutions. In order to help EURORDIS’ members and other interested parties to understand the issue, as well as EURORDIS’ position, we have developed this Q&A, at the best of our current knowledge on 8<sup>th</sup> March 2013. This [Regulation](#) proposal is very complex, and written in a dense legal language which is unavoidable for this issue, though unfortunate for a legislative text so important for all EU citizens, for which approximately 4000 amendments (!) have been tabled by the Members of the European Parliament. In this context, EURORDIS is still in the process of consulting both internally and externally, therefore this Q&A may evolve in the coming weeks. Your comments on the Statement as well as on the Q&A are welcomed and can be sent to [eurordis@eurordis.org](mailto:eurordis@eurordis.org).

## **Questions & Answers on the revision of the personal data protection directive: processing and free movement of data (General Data Protection Directive) March 2013**

### **Why is the revision of the Data Protection Directive needed?**

The European Data Protection Directive of 1995 (Directive 95/46/EC) set a milestone in the history of the protection of personal data. Its main objectives were: to guarantee the free flow of personal data between EU Member States (internal market) and to ensure an effective implementation of the fundamental right of individuals to the protection of their personal data. The basic principles included in the 1995 Directive are as valid today as they were 18 years ago.

Nevertheless, this legal framework has not prevented fragmentation in the way personal data protection has been implemented across the EU because of the differences in the way that each country has applied the law at national level. This has led to an uneven level of protection for personal data, depending on where an individual lives.

**This is why EURORDIS, the European Organisation for Rare Diseases, welcomes the proposal for a [Regulation](#), which is directly applicable in the national legislative frameworks, versus a Directive, which still needs to be transposed at national level, leaving national legislators room for interpretation and carrying a higher level of discrepancies in the implementation phase. Legal certainty, backed by a stronger and more coherent data protection framework, was felt to be needed at EU level.**

Furthermore, **the current rules also need to be modernised** as they were introduced when the Internet was still in its infancy. **Rapid technological developments and globalisation have brought new challenges with dramatic impact on the data protection debate.** In this new scenario a robust, clear and harmonised set of rules is needed.

The EU data protection reform has the ambition to put in place rules that are future-proof and fit for the digital age. Personal data protection plays a central role in the Digital Agenda for Europe, and more generally in the Europe 2020 Strategy.

### **What is the difference between a Regulation and a Directive?**

A **regulation** is a legislative act of the European Union that becomes immediately enforceable as law in all Member States simultaneously. Regulations can be distinguished from directives, which, at least in principle, need to be transposed into national law. Regulations can be adopted by means of a variety of legislative procedures depending on their subject matter.

A **directive** is a legislative act of the European Union, which requires Member States to achieve a particular result without dictating the means of achieving that result. It can be distinguished from regulations, which are self-executing and do not require any implementing measures. Directives normally leave Member States with a certain amount of leeway as to the exact rules to be adopted. Directives can be adopted by means of a variety of legislative procedures depending on their subject matter.

### **What is meant by personal data?**

Personal data is defined as any information relating to an individual, whether it relates to his/her private, professional or public life. It can be anything from a name, a photo, an email address, bank details, individual posts on social networking websites, medical information, or computer's IP address. The EU data protection rules apply when a person can be identified, directly or indirectly, by such data.

The EU Charter of Fundamental Rights stipulates, in its Article 8 on the Protection of personal data, that:

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

### **Data traceability glossary (1)**

**Identifiable data:** data including information in patient records such as names, addresses, dates of birth. There are also aspects of health data that could become identifiable when they relate to a diagnosis of a rare disease or when combined with other data. Identifiable data are needed when future contact is established with the participant, for example to contact them to take part in a study, or to link information across different data sets.

**Pseudonymised (or key-coded) data:** these cannot directly identify an individual, but are provided with an identifier that enables the patients' identity to be re-connected to the data by reference to separate databases containing the identifiers and identifiable data. Pseudonymised data can often – but not always - be used in place of identifiable data.

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<sup>1</sup> FEAM Statement on the Data Protection Regulation, June 2012

**Anonymised data:** these data cannot be connected to the original patient record. Anonymised data are suitable when no contact is needed with the participant or where the data do not need to be linked to any other data sources.

## What is the European Commission proposing?

The European Commission is proposing to update and modernise the principles contained in the Data Protection Directive from 1995 in order to guarantee the right to personal data protection in the future with a new legal framework consisting of two legislative proposals:

- **a proposal for a Regulation** of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data, the so-called General Data Protection [Regulation](#) (this is the piece of legislation on which EURORDIS' action has been focusing);
- **a proposal for a Directive** of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offenses or the execution of criminal penalties, and the free movement of such data (EURORDIS has not been addressing this legislative proposal which is beyond the remit of its competence).

These new frameworks will focus on: reinforcing individuals' rights; strengthening the EU internal market; ensuring a high level of data protection in all areas; ensuring proper enforcement of the rules; and setting global data-protection standards.

## What are the key changes proposed?

The [Regulation](#)'s overarching goal is to protect individuals with regard to the processing of personal data and the free movement of such data. The proposed legislation will implement and substitute the current Directive introducing the following main elements:

- **A single set of rules** on data protection, valid across the EU.
- The data subject's "**right to be forgotten and to erasure**" will help people better manage data-protection risks online. When they no longer want their data to be processed and there are no legitimate grounds for retaining it, the data will be deleted.
- **Whenever consent is required** for data processing, it will have to be given **explicitly**, rather than be assumed.
- Access to one's own data will be easier and there will be a **right of data portability**, i.e. to **transfer personal data from one electronic processing system to another**, namely from one service provider to another, without being prevented to do so by the controller.
- Companies and organisations will have the **obligation to notify personal data breaches** without undue delay, where feasible within 24 hours.
- **Companies** will only have to deal with a **single national data protection authority** – in the EU country where they have **their main establishment**.
- Individuals will have the **right to refer all cases to their home national data protection authority**, even when their **personal data is processed outside their home country**.
- **EU rules will apply** to companies not established in the EU, if they offer goods or services in the EU or monitor the online behaviour of citizens.

- Increased **responsibility and accountability** for those processing personal data: obligation for the controller to comply with this [Regulation](#) and to demonstrate this compliance.
- **Unnecessary administrative burdens** such as notification requirements for companies processing personal data **will be removed**.
- **National data protection authorities will be strengthened** so they can better enforce the EU rules at home.

### What is the procedural pathway that the proposed legislation has to go through?

**The Report by the European Parliament Rapporteur Jan Philipp Albrecht (Greens/European Free Alliance, Germany) was released on 16 January 2013.** Following the publication of the Albrecht Report, amendments to the proposal from the Commission have been tabled and currently (March 2013) undergoing the translation process by the jurist-linguists of the European Parliament. **The vote for adoption by the responsible Committee of the EP (the LIBE Committee for Civil Liberties, Justice and Home Affairs) will take place in April 2013.**

The [Regulation](#) will be adopted by co-decision procedure and there will therefore be two readings by the European Parliament. The vote by the plenary in first Reading is scheduled for June 2013, while the second Reading and final adoption should be accomplished by the end of the year 2013.

### What has been EURORDIS' evaluation of the proposed General Data Protection [Regulation](#)?

EURORDIS has evaluated the text of the proposed [Regulation](#) taking advantage of its partnership in the EU Program of Community Action in the field of Public Health [EPIRARE](#) project (European Platform for Rare Disease Registries) in which a specific work package (WP4 – Legal basis) aims at assessing the most suitable EU legal instrument to allow for registration of patients' health data keeping in mind the interests of rare disease patients and the maintenance of a robust and ethical research environment, as well as from its partnership in other relevant health research and public health projects.

**The proposals of the European Commission for the revision of the Data Protection Directive from 1995 are overall welcomed by EURORDIS, but there is a need for some following clarifications in the proposed [Regulation](#) to improve the position of medical research, and in particular research into rare diseases.**

1. EURORDIS welcomes the sharpening of the existing definition of "research route" to fair, transparent and legal processing. The inclusion of **medical research** as an accepted route to fair and lawful processing of data is welcome and must be maintained in the [Regulation](#). However, this needs clarification in some key points, for example:
  - Whereas information gathered specifically for research can use Article 6(2) as the route to fair and lawful processing, when research is a further processing, Article 6(4) indicates that one of the other routes in Article 6(1) (a) to (e) must be used. Why is medical research not clearly specified as an appropriate route **also for further processing**?
  - Why does the proposed [Regulation](#) not contain a clear definition of compatible processing in the proposed Article 9, in relation to **sensitive personal data**, including genetic data? A specific reference to a health research as a valuable route for justifying lifting the ban on the processing of sensitive personal data would be fundamental for research in the area of rare diseases.

- Under Article 14, a data controller who collects data directly from a data subject must provide him/her with a list of information as specified from paragraph (a) to (h), including the controller's identity, contact details and the purposes of processing. This right of the data subjects to information has been considered as representing a problem in situations where this notification would create a “**disproportionate burden**” thereby preventing research from going ahead. This “disproportionate effort” provision only applies where the data are not collected directly from the data subject.
2. The inclusion of power to the European Commission to develop best practice guidelines for different aspects of the [Regulation](#) is very welcome, and we urge decision-makers to ensure that the area of rare diseases, and related medical purposes such as biobanking, is one of the first areas to develop best practice protocols with the invaluable contribution of all relevant stakeholders in the rare disease community.

### What has been EURORDIS proposal for amendments?

EURORDIS in coordination with the EPIRARE project has proposed amendments that argue for the following:

- It is important for research in rare diseases (and for other modern medical research techniques reliant upon large-scale data processing, for example in biobanking), that secondary processing of personal data can be undertaken under the original route to fair, lawful and transparent processing. In order to balance the interests of the data subject and other rights holders in the community, **alternative safeguards** must be in place to justify the appeal to compatibility with original purposes, for example, approval by an independent research ethics committee. It does not remove the separate requirement to inform the data subject about the processing (under Article 14), but it does not imply that a new specific informed consent is required. Notification under the information principles could be in these circumstances satisfied by, for example, the publication of information in a newspaper, and on a dedicated website (Justification to amendment of recital 122, Compatibility of Medical and Public Health Research with other purposes).
- Extended definition reflecting the current scientific understanding of the term “**data concerning health**”: this term means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual, including all elements related to health, namely health status, including morbidity and disability, the determinants, *including genetic data*, having, *or suspected to have*, an effect on that health status, health care needs, resources allocated to health care, the provision of, and access to, health care as well as health care expenditure and financing, and the causes of mortality (Amendment to Article 4(12)).
- Amending Article 5(b) to reinstate the wording of the current Directive [95/46/EC, Article 6(1) (b)] reintroduces the ambiguity of the current law. This would hinder the desired harmonisation efforts. **Article 5(b) should be kept without amendment to the proposal of 25-01-2012.** (Justification to amendment of Article 5, **Compatible Processing**).
- Whereas the current Directive (95/46/EC) Article 6(1) (b) is ambiguous about compatible processing, the proposal for the Regulation from 25 January 2012 removes the ambiguity. The Draft Regulation's Article 6(4) makes it clear that processing for compatible purposes is possible. Article 6(4) should be kept to the form of the Regulation published on 25-01-2012; it should include processing for (medical) scientific research by avoiding specifying the particular elements

of paragraph 1 that should be included (Justification to amendment of **Article 6(4) Lawfulness of Compatible Processing of Personal Data**).

- Whereas the text of Article 9 implies that the restriction on the processing of special categories of personal data can be lifted in the circumstances listed in 9(2) and so should include the further processing of special categories of personal data for purposes that are compatible with the original purposes for processing, making it explicit that paragraph 1 is also lifted in relation to processing for purposes that are compatible with the original purpose for processing will ensure that this is clear. This is important for much of modern health research and public health work (Justification to amendment of **Article 9, Lawfulness of Compatible Processing of Special Categories of Personal Data**).
- The proposals to delegate powers to the Commission to specify criteria and requirements for processing are enormously important in developing best practices in particular areas, and these powers should be included in the Regulation, as they allow for the development of 'best practice' protocols under the Regulation. Rare Disease research and public health processing should be a focus for these powers and best practice development in the early rounds of this process (Justification to amendment of **Article 86 (generally) and Article 83(3) (specifically), ensuring the inclusion of delegated powers to the Commission to develop best practices**).

#### **Why there is concern on the final content of the [Regulation](#)?**

The Report, released on 16 January 2013, by the Rapporteur Jan Philipp Albrecht (Greens/European Free Alliance, Germany) from the responsible EP Committee has raised concern. If the amendments proposed in this Report were adopted, there would be serious implications for health research, starting from the disconcerting premise that: *“Processing of sensitive data for historical, statistical and scientific research purposes is not as urgent or compelling as public health or social protection. Consequently, there is no need to introduce an exception which would put them on the same level as the other listed justifications.”* This premise is the justification from the Rapporteur to his Amendment 27 on the proposed Recital 42.

Among the 350 amendments proposed by the rapporteur if crucial ones were to be accepted (e.g. Amendments 13-14; Amendment 27; Amendments 84-85; Amendments 327-328; Amendments 334-337) the major concern is that they would mean that non-identifiable health data concerning an individual could never be used without their consent. This would mean that much important epidemiological research could not take place. For example, it would outlaw any registry-based research, such as research using cancer or disease registers.

The amendments would allow Member States to pass a law permitting the use of pseudonymised/key-coded data without consent, but only in cases of “exceptionally high public interest” (Amendment 27; Amendments 327 and 328; Amendments 334-337). This would be an impossibly high bar for all but the most exceptional research, such as that on bioterrorism.

In addition, the amendments would bring all pseudonymised/key-coded data within the scope of the Regulation, even where the person or organisation handling the data does not have the key. This would significantly increase the regulatory burden on organisations using pseudonymised data or sharing these data with collaborators in countries outside the EU (Amendments 13, 14, 84 and 85). This would have implications not only for the 27 Member States but also for accessing countries implementing the *acquis communautaire* and for those in other countries collaborating with EU researchers. **This would represent a major setback especially for research on rare diseases where collaboration and optimal use of scarce resources and data are particularly necessary at both the European and International levels.**

**Therefore, missing the opportunity of exploiting and sharing the limited amount of data that are collected would dramatically delay the improvement of health care for European**

**citizens living with a rare disease. It would *de facto* result in discrimination against rare disease patients regarding their fundamental right to quality health care and would pose serious ethical problems.**

### **What are EURORDIS' core messages?**

EURORDIS, gathering the support of several European Institutions and Research Consortia, as well as support of Patients Organisations from other regions in the world, has released a Statement voicing the concern of the Rare Disease Community at large with the aim to reach out to Members of European Parliament discussing the legislation in the coming months. The Statement's main messages are the following ones:

1. It is essential that **Article 83 on processing for historical, statistical and scientific research purposes** and the associated derogations that facilitate research are maintained within the Regulation, as pertains to health and sensitive data;
2. Some amendments are needed in order to clarify and strengthen the research provisions and make sure that the Regulation establishes a **health research-friendly framework in Europe** while striking the right balance with personal data protection;
3. The scope of the Regulation should be clarified in order to ensure that the use of **pseudonymised data** in health research is regulated in a proportionate manner.

**It is of fundamental importance to balance privacy rights with the right to protection of health and to bear in mind the ethical value of solidarity in sharing data to provide better health to others.**

**Health research is essential for public health and health care. The benefits are manifold: to capitalise on these benefits, it is vital that the EU strikes an appropriate balance between facilitating the safe and secure use of patient data for health research and the rights and interests of all individuals.**