EPF Brief on the Proposal for a General Data Protection Regulation

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At which stage of the process are we?

- The European Parliament adopted a first reading position on 12 March 2014. [1]
- Then the Council has adopted a partial general approach in December 2014. [2]
- There is political will to adopt the legislation in 2015, the indicative calendar says it should be adopted by June, but it is still very tentative.

What is at stake for patients?

- For patients, it is important that the Regulation reaches the right balance, protecting their privacy rights, but also **allowing data processing** to continue for healthcare, public health and research purposes.
- There are a lot of debates about **consent**, and whether it should always be specific and written, or if one-time consent should be allowed for health research.
- In addition, the proposal of the Commission also promoted the **right to have access** to one's own health information, and also the right to have a copy of one's own data in a portable format (e.g. that could be shared with another doctor). EPF supports the right of patients to have access free of charge to their health records.
- The proposal also gave **improved rights to citizens to be informed** of how their data are used.

Key challenges that have come up during the legislative process:

- Questions around **health research** have not been given a lot of focus by decision makers, due to debates in other areas, as this Regulation is general and cover other domains besides health.
- The European Parliament proposed to remove possibilities for **exemption from the obligation to seek specific consent** for health research which were in the Commission's proposal. It is also restrictive on instances where researchers could use pseudonymised data[3] instead of anonymous data.

[1] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN

[2] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2016140%202014%20INIT

[3] Pseudonymised data are key-coded data; they are anonymised, but researchers can re-identify the data with a key kept separately if needed.

- EPF position is that informed consent is a fundamental right and should be the rule, but exemptions are needed in some cases when it's practically impossible to consent or re-consent research participants.
- EPF also expressed concern that new data protections rules should not lead to more **fragmentation** across the EU on consent rules.
- To raise awareness of decision makers on these issues, EPF has joined a **campaign** with non-for-profit-research organisations and public health NGOs http://www.datasaveslives.eu/
- The campaign has listed case of research that would have been hampered with an obligation to seek specific consent: http://www.datasaveslives.eu/case-studies/ . It also explains that other safeguards exist for patients' privacy.

Do patients still need to give input or advocate with decision makers?

- Patients and patients' representatives wishing to show their support for the datasaveslives campaign can participate: more information available here
- It is still time for patients' organisations to share their perspectives with MEPs (LIBE committee) and the Council (Ministry of health and/or Ministry of Justice)

Useful links

- EPF webpage on data protection, where you can find the EPF position statement: http://www.eu-patient.eu/whatwedo/Policy/Data-Protection/
- European Data in Health Research Alliance: www.datasaveslives.eu twitter.com/datamattersEU @datamattersEU
- Brief on the Datasaveslives campaign: http://www.eu-patient.eu/Members/Weekly-Mailing/show-that-patients-want-to-share-our-health-data-to-improve-research/
- "Research projects can change patients' lives", Nick Meade, EPF blog: http://www.eu-patient.org/blog/?p=260
- List of LIBE committee MEPs: http://www.europarl.europa.eu/committees/en/libe/members.html