

11 March 2013, Brussels

Subject: Plenary vote on the Regulation on Data Protection

Dear Member of the European Parliament,

We are writing on behalf of the European Patients' Forum to ask for your support in the upcoming debates and vote the proposal for a Regulation on Data Protection. It is of vital importance that this legislation strikes the right balance between guaranteeing patients' fundamental right to protection of their personal data while ensuring these data can be processed for research and health purpose. Yet several changes made by the LIBE report could negatively affect health research.

We are supportive of changes in the Regulation to foster more transparency and information to EU citizens on data processing, and that promotes right to access one's own health data and data portability.

But one key provision introduced in the proposal was removed in the LIBE report in Article 81: the draft Regulation made it clear that processing data for **patient registries** is lawful. In our view the Regulation should explicitly require Member States to cooperate to remove obstacles that hamper the setting up of patient registries, which are vital tools. They are used to study the prevalence and incidence of diseases, for monitoring the safety of products and interventions, assessing clinical effectiveness of interventions in real-world settings, in planning services and assessing their quality, etc. They play an essential role in creating contact between patients and researchers or authorities for clinical trials and other purposes.

We also believe that the articles regarding research and consent for the purpose of **health research** should to be re-examined. Patients are increasingly aware of the value and importance of sharing their data. From the patients' perspective, use of health and genetic data is vital to advancing health research – this includes public health, medical and social science research (including psycho-social research). This is both in the patient's interest and for the benefit of the wider community.

In our view the proposal to have exemptions from **consent** obligations only when there is a "high public interest", to be decided by Member States in their national legislation will lead to even more fragmentation as regards consent rules across the EU. We believe questions of consent for health research, including whether to allow "broad consent", would be addressed more adequately in the implementation of the recently adopted Clinical Trials Regulation, through adopting guidelines in consultation with stakeholders in the health sector, including patients' organisations.

While we support the reform which you will be voting on on 12 March, we strongly recommend you consider the above questions in the negotiations with other institutions after the vote. We thank you for your attention and remain at your disposal for more information or in case of any queries.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'A. Olauson', is positioned below the text 'Yours sincerely,'.

Anders Olauson, EPF President

The **European Patients' Forum (EPF)** was founded in 2003 to ensure that the patients' community drives policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens in the EU. EPF currently represents 62 member organisations, which are national coalitions of patient organisations and disease-specific patient organisations working at European level. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe.

EPF's vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centred and equitable health and social care.

The EPF strategic goals focus on areas such as health literacy, healthcare, patients' involvement, patients' empowerment, sustainable patients' organisations and non-discrimination.

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