



EPHA Position on EU Data Protection Reform

November 2012

EPHA is a change agent – Europe’s leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe.

Our mission is to bring together the public health community to provide thought leadership and facilitate change; to build public health capacity to deliver equitable solutions to European public health challenges, to improve health and reduce health inequalities.

Please see www.ephha.org for more information.

At time of writing, the European Commission (EC) is reviewing its existing legal framework on data protection to ensure that the rules are fit for dealing with increasingly complex and sophisticated developments in technology and data usage. The ambitious legislative proposal for a **Regulation on General Data Protection**¹ proposes harmonisation rules for many data areas – including in the area of health – with implications for individuals, companies and public authorities.²

EPHA supports the aims and objectives of the Commission’s draft proposal and acknowledges the weaknesses of the existing legal structure. The proposal attempts to balance the individual’s fundamental right to data protection with need for free flowing information in a single European market – from a public health perspective the primary concern, as highlighted in the opinion of the European Economic and Social Committee (EESC), is that this balance is currently uneven, favouring the latter over the former.³

¹ See http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

² For further background information, see the EPHA briefing www.ephha.org/a/5211

³ EESC Opinion 23 May 2012

<http://eescopinions.eesc.europa.eu/eescopiniondocument.aspx?language=EN&docnr=1303&year=2012> point 3.9

The **definitions and scope** of the Regulation require adjustment in some cases; specifically, the notion of ‘transfer of data’ should be sure to include non-ICT based data, whilst the definition of ‘data concerning health’ differs between Article 81 and Recital 26 in terms of its inclusion of biological samples. EPHA feels that the scope of the Regulation should be broadened to include social networking sites and search engines, and that provisions should be put in place that allows adaptability to cloud computing and future technological developments, ensuring that the Regulation is fit to address the challenges of twenty-first century progress. Finally, the intended implications for pseudonymised data and the process of anonymising data should be clarified.

EPHA⁴ strongly supports the **provisions** enshrining the right to access (Art 15) and transparent information and communication (Art 11) and urges that these provisions be upheld, along with the prohibition on tracking and profiling software on health-related websites. In addition, Article 83 and its associated derogations must be maintained and clarified so as to facilitate health research. However, some consideration should be given to the burden implied by the set of requirements attached to Article 15, which many organisations would struggle to supply. Furthermore, it is vital that only health professionals are able to access certain types of health data, and that the Regulation acknowledges the importance of digital literacy in enabling both citizens and professionals to observe its provisions. EPHA also supports the Article 17 provisions on the right to be forgotten, but believes it is vital to balance the right of the individual against the retention of certain data by public authorities where it might be used in the public interest⁵ – for example in the prevention of public health risks. The articles on the right to request and the role of individual data protection officers in documenting data processing do raise some concerns, since they put great burden on healthcare organisations and providers, which deal with a mixture a electronic and non-electronic sources and process very large volumes of data. Finally, EPHA supports the proposal’s attempt to highlight the necessity of consent, which becomes even more important where data processing involves vulnerable groups like children, but notes that a ‘one size fits all approach’ is not appropriate and that levels of digital literacy, and competency to consent - with the right to withdraw consent - must be taken into account. This should go hand in hand with increasing awareness about data subjects’ and data processors’ rights and obligations.

As regards the **derogations and exemptions** foreseen by the draft Regulation, EPHA encourages clarification and notes the concern that these are excessive in number.⁶ The conditions where the rights of the data subject are to be restricted must be better defined, as must the meaning of ‘legitimate/public interest’ as a justification in these cases. The exemptions regarding employment (special conditions in Arts 81, 83 and 9.2) must be made clearer – the sharing of data between employers of health professionals is vital in order to maintain patient safety, particularly in light of increasing professional mobility and the free movement of health professionals around Europe.

⁴ Whilst the majority support the provisions of Articles 15 and 11, the EPHA membership is not in complete accord on this aspect of the proposed Regulation. Concerns about the overly prescriptive nature of the Commission proposal in Article 15 are elucidated by the Royal College of Physicians, for example, and can be found here <http://www.rcplondon.ac.uk/sites/default/files/documents/rcp-position-statement-ec-reform-data-protection.pdf>

⁵ This said, EPHA also acknowledges the need to enshrine personal data protection as a fundamental right and not just a means to economic growth, see <http://www.aedh.eu/Personal-data-protection-must.html>

⁶ EESC Opinion 23 May 2012 footnote 3, point 1.3

Furthermore, EPHA highlights the need for certain, well-defined exemptions as regards data for health research, in particular clinical trials, to ensure that policy-makers and health professionals retain access to a broad range of studies on health and medicine⁷.

EPHA supports the strict **enforcement** of data protection rules and the consistent upholding of citizens' fundamental rights, as outlined in the Commission proposal. However, the blanket requirements for processing put great pressure upon individual organisations. In particular, as noted above, the requirements put upon data controllers in the processing procedures are disproportionately burdensome for health providers⁸. This is of particular importance in light of the Cross-Border Healthcare Directive⁹, which will see an even greater volume of data transferred and stored at an even greater number of locations. The fines imposed upon data controllers in these cases, whilst serving to encourage compliance, could be very damaging and such provisions might therefore be restructured to account for the difficulty in transferring data within the time limits prescribed¹⁰. Also in relation to data portability and cross-border healthcare, the liability of data controllers in the transfer of data to third parties is not clearly addressed in the proposal. Though a patient can request to have their data sent on to another processor or controller, it is not apparent with whom responsibility lies to ensure this is completed securely. Finally, whilst EPHA supports the creation of codes of conduct (Art 38) and the sharing of best practice in this area, it highlights the need for a high level of protection for both data controller and data subject, as well as appropriate and independent oversight and complaints procedures.

Looking to the **future development** of the proposed Regulation, EPHA notes the need for any legal framework to be flexible and able to react to changes in technology and national situations. For this reason, EPHA supports the degree of autonomy assigned to national supervisory authorities, so as to reflect and incorporate national divergences in the field of data protection and processing. However, EPHA takes special note of broadly held concerns about the number of delegated acts provided for in the proposal. In addition to assigning undue influence to the Commission and arguably sitting outside of the scope of Art 290 TFEU¹¹, such a pattern indicates a set of weaknesses in the current proposal. In order to best protect individuals and public health at large, EPHA encourages the creation of a comprehensive and far-sighted regulation from the outset, whilst building in the necessary provisions for timely adaption and update.

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⁷ Joint Statement on Data Protection – Cancer Research UK et al

http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/publication/cr_086673.pdf

⁸ See Position of the Royal College of Physicians, footnote 4

⁹ Directive on the application of patients' rights in cross-border healthcare <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

¹⁰ AIM-ESIP Joint Position Paper http://www.aim-mutual.org/uploads/documents/pub-273_en-aim-esip_position_paper_on_data_protection.pdf

¹¹ See EESC Opinion 23 May 2012 footnote 3, point 1.6