A response by the European Public Health Association to the report by the European Parliament's Committee on Civil Liberties, Justice and Home Affairs report on the proposal for a General Data Protection Regulation (2012/0011(COD)

21 February 2013

The European Public Health Association, representing 41 national public health associations with over 14,000 members, welcomes the proposal by the European Commission to propose a Data Protection Regulation (2012/0011(COD) that seeks to create a proportionate mechanism for protecting privacy, while enabling health research to continue. In particular, the clarity provided by these proposals will make it possible for high quality research that will benefit their citizens to be undertaken in some Member States where this has not previously been the case. However, we view with the utmost concern the amendments set out by the Committee on Civil Liberties, Justice and Home Affairs of the European Parliament in their report dated 16.1.2013. These amendments would mean that:

- Data concerning health could only be processed for research with the specific, informed and explicit consent of the data subject (amendments 27, 327 and 334-336)
- Member States could pass a law permitting the use of pseudonymised data concerning health without consent, but only in cases of "exceptionally high public interest" (amendments 328 and 337)
- Pseudonymised data would be considered within the scope of the Regulation, even where the person or organisation handling the data does not have the key enabling reidentification (amendments 14, 84 and 85)

The consequences of these amendments for health research would be disastrous, a description that we do not use lightly. If implemented, they would prevent a broad range of health research such as that which has contributed to the saving of the lives of very many European citizens in recent decades. We are concerned that these amendments must reflect a misunderstanding of the nature of health research and the central role played by data in undertaking it, and in particular our evolving understanding of the crucial importance of obtaining unbiased and representative data on large populations so as to minimise the risk of reaching incorrect conclusions that could potentially lead to considerable harm to patients.

The Committee's proposed amendments do not take account of how health research using personal data is undertaken within a well-established ethical framework, set out in the *Declaration of Helsinki*, and operationalised in many national standards. These standards ensure that an individual's personal data are only used in research when to do so is proportionate to the potential benefits for society as a whole. Such research must be approved by an ethics committee, which has members that are independent from the researchers or their employers, and provides a valuable safeguard.

These ethical principles make clear that data should only be used with the consent of the individual concerned, something which researchers fully endorse. However, the amendments propose qualifying such consent, requiring that it be "specific, informed and explicit". Some of the greatest recent advances in our understanding of the determinants of health and the mechanisms underpinning them have come from large

scale studies in which individuals have enrolled, after giving informed consent, in the knowledge that the data gathered can be used for a range of different studies, including those seeking to understand diseases which may not, at the time of enrolment, even be known about. In such studies, the data are anonymised or pseudonymised, and there is now a wealth of experience in methods of pseudonymisation of personal data that can protect individuals' privacy, while retaining the usefulness of the data. Obviously, such research requires robust data security procedures, with researchers subject to strict duties of confidentiality, enforced by regulatory bodies and legal sanctions. However, these are well established and we are unaware of any case in Europe where these requirements have been breached in living memory.

The task of setting up studies and ensuring follow up of those recruited (examples include the Biobank studies) can be enormous but the benefits are correspondingly great because of the scope to use the data that have been made available to answer newly emerging questions. This would not be possible (or affordable) if each researcher using the data had to contact every participant to obtain permission for every study. Crucially, even if it was possible, and affordable, to seek to contact everyone, this would inevitably lead to the systematic exclusion of those who are no longer traceable. This will disproportionately exclude those who are the most disadvantaged who often have the most to gain from health research. It will also increase risk of biased and misleading results. These issues are addressed by ethics committees ensuring that data are used in an ethical manner.

We can illustrate our concerns with a few examples, drawing in particular on the experiences of the Nordic countries that are among the most advanced in such research anywhere in the world. A study using Danish registry data identified the increased risks of heart attacks among those taking certain drugs used widely for arthritis. The subsequent changes in practice undoubtedly saved many lives. A Finnish study showed how the prescribing of certain tranquilisers to patients with schizophrenia increased the death rate by 90%. Again, the subsequent changes in practice saved many lives.

The Commission's proposal recognises that it will sometimes be necessary for data to be used in these ways. However, the committee's amendments greatly restrict the scope for exemption from the general principle. If passed, the amendments would limit the ability of Member States to provide an exemption from consent only where there is "exceptionally high public interest". Existing safeguards ensure that health research serves the public interest. However, the words "exceptionally high" envisage that this exemption would be used only in a very limited set of circumstances. This would require that the results and their implications for policy and practice be known at the outset, which is clearly not possible.

A further implication of the amendments is that researchers would no longer be able to identify individuals who could be requested to take part in a research. Epidemiological research often requires the identification of individuals with particular characteristics, for example a particular disease, or of a particular age or sex, or living in a particular area. This is especially important where research is seeking to understand possible environmental determinants of a rare disease, such as the suggested association between power lines and childhood leukaemia. For the necessary research to be valid it is essential to obtain a register of cases of leukaemia that is as complete as possible; to miss even a few cases could easily produce an entirely incorrect conclusion, with profound implications for policy. It is also important to have information on the pool of people from whom one wishes to recruit for inclusion in trials of new treatment, to ensure that those participating are representative of those who will ultimately obtain that treatment. Decades ago, it was common only to recruit working age men into studies of the causes of heart disease, giving rise to quite misleading results. However, without data on the characteristics of the population and their health, it would be easy to obtain extremely biased samples that would exclude older people or those who were materially disadvantaged, again giving the wrong answer, with potentially fatal consequences.

We understand the need to strike an appropriate balance between the societal need for research that can promote the health of Europe's citizens and the mechanisms that ensure the safe and secure use of

patient data in health research and the rights and interests of individuals, while noting that they themselves have an interest in being able to benefit from treatment based on research. We believe that the Commission's proposals achieve this balance but that the proposed amendments do not and, if passed, they would have profoundly damaging implications for the future health of Europe's citizens.

Professor Walter Ricciardi
EUPHA President

Professor Martin McKee
EUPHA President Elect

To contact EUPHA please e-mail: office@eupha.org

Note: further information on the adverse consequences of the proposed amendments can be found at http://allowresearch.com/about/