

Proposal of the International Epidemiological Association (IEA) on the proposed General Data Protection Regulation (GDRP) of the European Parliament and of the Council of the European Union.

With reference to text of the GDRP as proposed by the European Commission (document COM(2012) 11 final – C7-0025/12 of 25.1.2012) and to the Draft Report by the Committee on Civil Liberties, Justice and Home Affairs of the European Parliament dated 16.1.2013 the International Epidemiological Association

observes that :

there is a general consensus among biomedical scientists and public health professionals that epidemiological research conducted in human populations is indispensable for identifying not yet discovered causes of existing common and rare diseases as well as causes of emerging disease; it is also indispensable to assess the effectiveness of preventive and therapeutic interventions. Optimal use of limited resources requires that health policies and decisions governing the health services are based on sound scientific evidence as provided by epidemiological research, which for this reason must be regarded as **research of the highest public interest**. To implement this research epidemiologists make use of modern technology that enables to develop systems guaranteeing a very high degree of personal data protection in full respect of citizens' fundamental rights.

IEA notes that :

this type of research often demands the use of personal data for which it is materially impossible to obtain the informed consent of the subject to whom such data pertain or the procedure to obtain the consent would distort the results of the research making them of no use for the health purposes that justify the research. To cite just a single but typical example an international (European) epidemiological project aims at measuring the excess risk of cancer, if any, in children who, for medical reasons, had to undergo one or more examinations with CT scan. This is precious information for guaranteeing a safe use of CT scans in clinical practice. The most informative population of children are those who received the examination one or two decades back in time when X-rays doses emitted by the CT machines were higher: to contact the parents or the children themselves (if now in the majority age) in order to obtain consent to the use of the data in their past medical records would inevitably lead to the loss of untraceable people. Not only this loss would reduce the size of the group of children under study, thus making more difficult to detect any adverse effect of the CT scan, but may completely distort the results if, for example, children who developed cancer would be easily traceable (because of hospitalizations) while a substantial proportion of children who did not develop a cancer could not be traced. An additional point should be noted: given the (relative) rarity of childhood

cancers a study of this type requires investigating a large population of children, hence the need of pooling together populations from various countries *provided of course that all those EU countries make accessible in the same way the necessary data.*

IEA proposes that in respect to the Amendments in the Draft Report :

- **Amendment 27 – Proposal for a regulation –Recital 42, should read (insertion in bold) :**
(42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular health purposes, including public health and **health related research**, and social protection and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for setting claims for benefits and services in the health insurance system.

- **Amendment 327 -Proposal for a regulation: Article 81-paragraph 2**
Amendment 328 -Proposal for a regulation: Article 81-paragraph 2a (new)
should both be DELETED.

IEA shares the view inspiring these two amendments, namely that health data are to be considered as extremely sensitive. However to make access to these data without the explicit consent of the subject to which they pertain possible only as an ‘exception’ granted by a Member State for research serving “exceptionally high public interests” poses as exceptional and extra-ordinary large sections of epidemiological research that instead represent –as noted above- an ordinary and indispensable tool for the identification of causal factors of diseases and for the evaluation of the performance and value of health services, as the bases for public health policies and for health services governance. In addition Member States may vary in their appreciation of “exceptions” and legislate differently in this respect : this may make impossible to combine data from different countries hampering – as again already noted- the conduct of large European studies.

Article 81 , paragraph 2, should read (changes in bold) :

Processing of personal data concerning health which is necessary for [DELETE :historical, statistical or scientific research purposes] **scientific research purposes of the highest public interest** , such as patient registries set up for improving diagnoses, **investigating disease causes**, and differentiating between similar types of diseases and preparing studies of therapies, is subject to the conditions and safeguards referred to in Article 83.

- **Amendment 336- Proposal for a regulation : Article 83-paragraph 1 a (new)**

Amendment 337- Proposal for a regulation : Article 83-paragraph 1 b (new)

Should both be DELETED.

The DELETION is proposed for strict consistency with the proposal of DELETION of Amendments 327 and 328 to Article 81.

Article 83 , paragraph 1 (a) should read (changes in bold) :

these purposes **are of the highest public interest and** cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject ; .



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