

COMP Article 81

16.10.2013

Article 81

Processing of personal data concerning health

1. ~~Within the limits of~~ **In accordance with the rules set out in** this Regulation, ~~and in accordance in particular~~ with point (h) of Article 9(2), processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable, **consistent**, and specific measures to safeguard the data subject's **legitimate** interests **and fundamental rights**, to the extent that these are necessary **and proportionate**, **and of which the effects shall be foreseeable by the data subject**, for:

(a) the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies; or

(b) reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical devices, **and if the processing is carried out by a person bound by a confidentiality obligation**; or

(c) other reasons of public interest in areas such as social protection, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system **and the provision of health services**. **Such processing of personal data concerning health for reasons of public interest shall not result in data being processed for other purposes, unless with the consent of the data subject or on the basis of Union or Member State law.**

1a. When the purposes referred to in points (a) to (c) of paragraph 1 can be achieved without the use of personal data, such data shall not be used for those purposes, unless based on the consent of the data subject or Member State law.

1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.

1c. For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC shall apply.

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, ~~such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies~~, **is shall be permitted only with the consent of the data subject, and shall be** subject to the conditions and safeguards referred to in Article 83.

2a. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data subjects. However, the data subject shall have the right to object at any time in accordance with Article 19.

3. The Commission shall be empowered to adopt, *after requesting an opinion of the European Data Protection Board*, delegated acts in accordance with Article 86 for the purpose of further specifying ~~other reasons of~~ public interest in the area of public health as referred to in point (b) of paragraph 1 *and high public interest in the area of research as referred to in paragraph 2a, as well as criteria and requirements for the safeguards for the processing of personal data for the purposes referred to in paragraph 1.*

3a. Each Member State shall notify to the Commission those provisions of its law which it adopts pursuant to paragraph 1, by the date specified in Article 91(2) at the latest and, without delay, any subsequent amendment affecting them.

Recitals

(122a) A professional who processes personal data concerning health should receive, if possible, anonymised or pseudonymised data, leaving the knowledge of the identity only to the General Practitioner or to the Specialist who has requested such data processing.

(123) The processing of personal data concerning health may be necessary for reasons of public interest in the areas of public health, without consent of the data subject. In that context, ‘public health’ should be interpreted as defined in Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work, meaning all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality. ~~Such processing of personal data concerning health for reasons of public interest should not result in personal data being processed for other purposes by third parties such as employers, insurance and banking companies.~~

(123a) The processing of personal data concerning health, as a special category of data, may be necessary for reasons of historical, statistical or scientific research. Therefore this Regulation foresees an exemption from the requirement of consent in cases of research that serves a high public interest.